

# Carbon Monoxide (CO) Protection for Escape Respirators

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**TDA**  
Research

## Abstract

First responders (policemen, firemen, etc.) are the men and women who are first on the scene of a disaster. There are 11 million state and local first responders in 87,000 jurisdictions throughout the United States. Escape hoods that are effective against chemical, biological, radiological and nuclear (CBRN) agents need to be developed and approved by NIOSH so that first responders may use them effectively.

TDA Research, Inc. (TDA) has collaborated with a major PPE (Personal Protective Equipment) manufacturer to develop a CBRN escape hood that will meet the recently announced standards by the NIOSH. In addition to CBRN protection, the escape hood will be designed to be effective against carbon monoxide (CO). In the Phase I SBIR project, TDA has designed, fabricated, and tested catalytic materials that were effective in removing CO at 0°C. TDA has tested the product successfully using NIOSH specified criteria. In the Phase II project, TDA will scale up the catalyst, optimize the composition and amounts, and test it in a canister at its collaborator's facilities.

## Introduction

When responding to hazardous situations such as fires or chemical spills, one of the primary concerns for first responders and civilians trying to escape is respiratory protection. While firefighters have access to SCBA, civilians and other potential first responders (police, paramedics, etc.) are typically not equipped with this type of long-term respiratory protection. As a result, short-term protection, such as gas masks or bottled air escape respirators, are used by those without access to SCBA.

One form of short-term respiratory protection is the air purifying escape respirator (Figure 1), which has been approved for chemical, biological, radiological, and nuclear (CBRN) hazard protection. The escape hood, made of a laminate material, is easy to put on and completely covers the head and neck. The contaminated air is breathed-in through a canister containing impregnated carbon, where it is purified, and exhaled air flows out of the hood through a separate valve to make breathing easier for the user. The escape hood is designed to provide ~15 minutes of escape time for first responders or civilians.



Figure 1. Escape hood.

The most common incidents resulting in the need for respiratory protection are fire related. In 2000, 1.7 million fires in the U.S. resulted in 4,200 deaths. A common cause of death in these instances is exposure to the hazardous compounds produced by a fire (Table 1), including carbon monoxide (CO). Though the escape hood described above provides effective protection against CBRN, it does not provide any protection against CO exposure. Furthermore, new NIOSH certification requires CO protection. As a result, technologies that will protect users against CO when using respiratory protection, such as the escape hood, are highly desirable.

Table 1. Typical contaminant levels in fire smoke.

| Contaminants                      | Typical Conc. (ppm) | Max. Conc. (ppm) | IDLH (ppm) |
|-----------------------------------|---------------------|------------------|------------|
| Acrolein                          | 1.9                 | 98               | 5          |
| Benzene                           | 4.7 – 56            | 250              | 3000       |
| CO                                | 248 – 1450          | 27000            | 1200       |
| HCl                               | 0.8 – 1.3           | 280              | 100        |
| HCN                               | 0.14 – 5.0          | 75               | 50         |
| NO <sub>2</sub>                   | 0.04 – 0.7          | 9.5              | 50         |
| SO <sub>2</sub>                   | 2.3                 | 42               | 100        |
| Particulates (mg/m <sup>3</sup> ) | 232                 | 15000            | n.p.       |

## Methods

TDA Research, Inc. (TDA), in collaboration with a major PPE manufacturer, is developing catalysts for the low temperature oxidation of CO to CO<sub>2</sub>. The inclusion of these catalysts in the carbon cartridge used in the escape hood will provide the wearer protection against dangerous levels of CO. Several of TDA's CO-oxidation catalyst formulations have been shown to successfully oxidize CO at low temperatures (Figure 2).

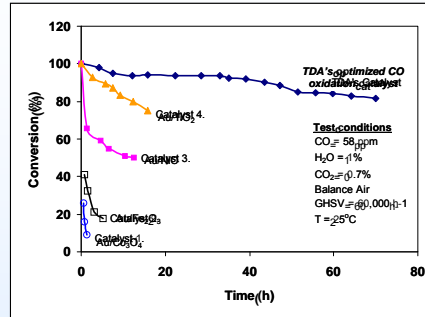


Figure 2. CO oxidation results for various transition metal oxide catalysts developed at TDA.

Based on these novel catalysts developed previously at TDA, catalyst compositions were further optimized for low temperature (0°C) oxidation of CO and screened under NIOSH specified conditions:

- 15 minutes of protection from 3,600 ppm of CO
- peak CO slip during 15 minutes should be no higher than 500 ppm
- testing to be done at 0°C with 64 slpm of air

Catalyst screening experiments were performed at TDA using a down-flow, fixed bed CO oxidation test reactor apparatus (Figure 3). The optimized CO oxidation catalysts were tested at GHSV of 30,000 to 120,000 hr<sup>-1</sup> under the specified NIOSH testing protocol.

Following catalyst screening experiments, TDA tested its best catalyst in a canister in accordance with NIOSH test protocols. In these tests, a canister was filled with carbon and TDA's CO oxidation catalyst. The canister was then hooked-up to a test apparatus and evaluated under the NIOSH conditions of 64 slpm of 0°C air containing 3,600 ppm of CO. The canister outlet was then monitored for CO using an infrared CO analyzer. Initial tests with the canister failed to meet the NIOSH prescribed CO slip in the first 2 minutes of the test. The composition of the canister was then modified, resulting in a successful test.

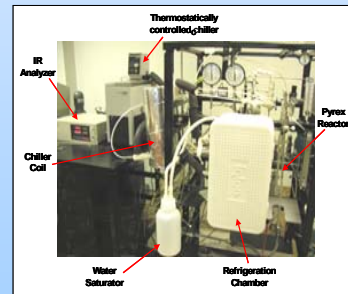


Figure 3. TDA's CO oxidation test apparatus.

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## Results

TDA screened CO oxidation catalysts in order to optimize its catalyst for operation at 0°C. Catalyst screening results using NIOSH testing protocols for TDA's best catalyst can be seen in Figure 4. In all cases, >80% of the CO was oxidized and 100% conversion CO was observed for our best catalyst.

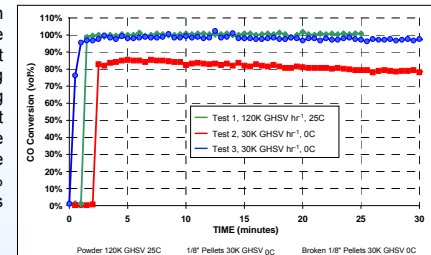


Figure 4. Catalyst screening results using NIOSH test protocols for TDA's best CO oxidation catalyst.

Prototype testing was performed with a canister using a NIOSH prescribed test apparatus. Results for initial testing under NIOSH test conditions are shown in Figure 5. As can be seen, the canisters containing TDA's CO oxidation catalyst failed the test due to CO spikes >500 ppm (NIOSH protocol #2) that occurred in the first two minutes of the run. In order to eliminate these CO concentration spikes, TDA further modified the canister content formulation in order to pass the NIOSH protocols. Figure 6 shows the results of repeated NIOSH protocol testing using the modified canister formulation. With the new canister, which included TDA's CO oxidation catalyst, TDA was able to eliminate the >500 ppm CO spikes, thus passing all NIOSH protocol for respiratory CO protection.

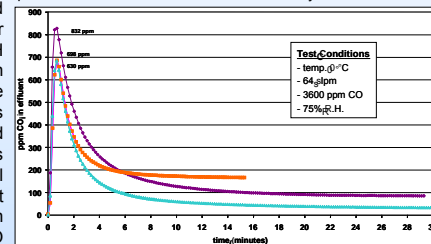


Figure 5. Initial testing results performed with a prototype respirator canister.

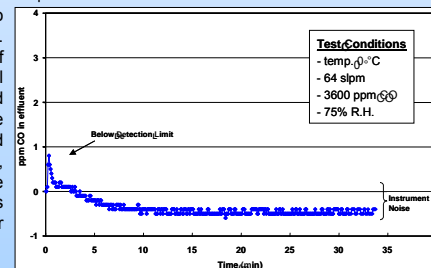


Figure 6. Prototype canister test results with TDA's modified composition, which passed NIOSH protocols.

## Conclusions

TDA, in collaboration with a major PPE manufacturer, has developed a CO oxidation catalyst that can be used in respirator cartridges to protect the user from dangerous atmospheric levels of CO. Results indicate that this approach will allow escape respirators to pass the NIOSH certification tests.

## Disclaimer

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

# NPPTL Certified Product Investigation Process (CPIP) of the NIOSH Respirator Certification Program

Kim C. Gavel and Lynn L. Rethi

## NPPTL Post Approval Programs

- Manufacturer Site Audit
- Certified Product Audit
- **Certified Product Investigation Process (CPIP)**
- Firefighter SCBA Evaluation (joint w/ NIOSH, DSR)
- Long Term Field Evaluation

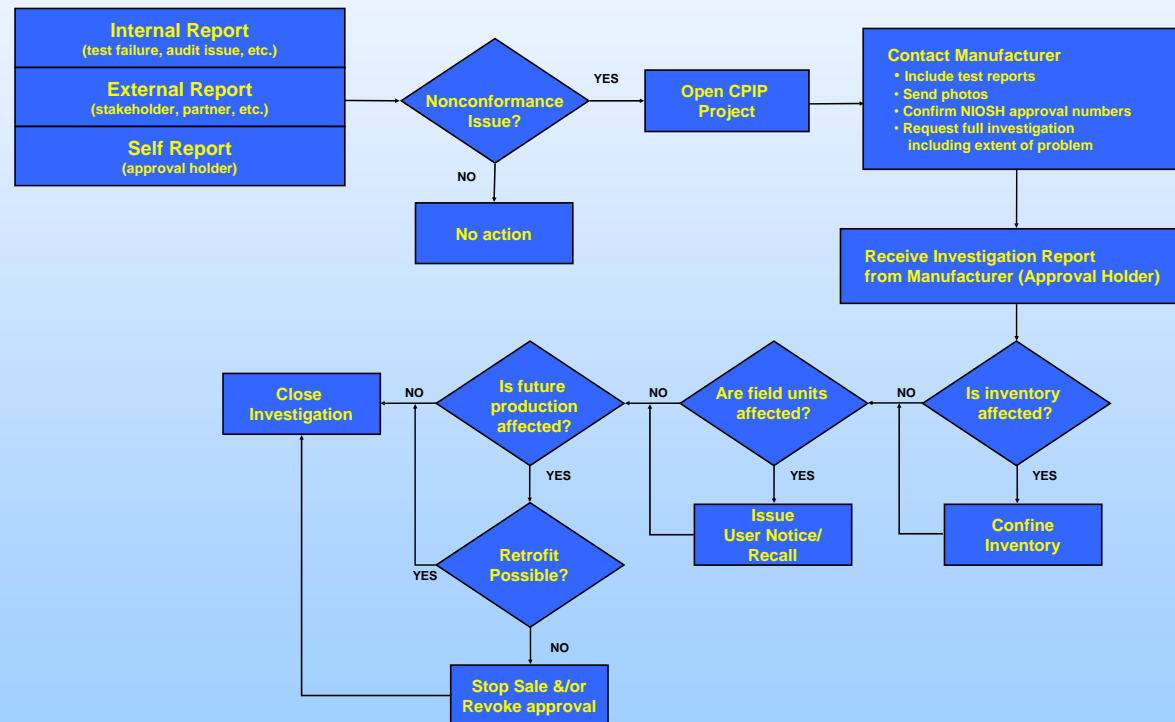
## CPIP Objective

To ensure the quality of NIOSH certified respiratory protective devices used in the field by investigating and resolving reports of product nonconformance issues in a timely manner.

## 2008 CPIP Outputs

- 14 Firefighter Reports Generated
- 16 Field Investigations Completed
- 10 User Notices Issued
- 2 NIOSH Approvals Revoked

## Overview of CPIP Process



## Stakeholders

- Respirator Users
  - Enforcement Agencies
  - Emergency Responders
  - Respirator Manufacturers - worldwide\*
- \* Since 2004, NIOSH has issued a total of 57 new manufacturer codes
- US – 26
  - Outside US – 31

## Key Partners

- NFPA
- IAFF
- SEI
- MSHA
- FDA
- EPA
- OSHA

## Outcome

To ensure that NIOSH approved respirator devices continue to meet or exceed the criteria on which the approval was based.

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# Evaluation of Respirator Filters for Asbestos Fibers

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## Abstract

Fiber aerosols are known to have different aerodynamic behaviors than spherical particles and usually carry higher electrostatic charges. We have investigated the effects of flow rate and charge status of filter cartridges on the penetration of spherical and fiber aerosols. Three types of test respirator filters were selected: one for passive respirators, one for a powered respirator, and one disposable face mask. Surface charges on respirator filters were determined using a non-contact field electrostatic field meter. Penetration tests were performed for filter cartridges before and after charge neutralization. The surface charge measurements on the respirator filters showed that some filters, including those used in disposable facemasks, are charged to enhance the collection efficiency. Our data also showed that the surface charges decreased in a 38°C and > 90% relatively humidity environment and disappeared after 1 week. Three asbestos fibers of different diameters were tested: an ultrafine chrysotile (Calidria); a UICC crocidolite; and a UICC amosite. Only high-efficiency particulate air filters performed consistently for both spherical test aerosols and the three types of asbestos fibers. The surface charge potential of filter cartridges and flow rate did not appear to affect the performance of these filters. In contrast to the high-efficiency filters, the aerosol penetration performance of low efficiency filters and face masks deteriorated when the charge potential on the filter was removed. (This research was supported by a National Institute for Occupational Safety and Health grant 1R01 OH03900).

## Introduction

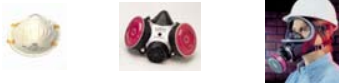
- Exposure by inhalation to asbestos fibers may lead to primary lung cancers, mesothelioma, and pulmonary and pleural fibrosis.
- Potential sources of exposure to fibrous materials in occupational environments will continue to increase.
- Respiratory protection is required to minimize exposure.
- Data are limited on fiber filtration through respirator filters.

## Objectives

- Study the performance of respirator filters using fiber aerosols.
- Understand the effects of fiber dimensions on collection efficiency.
- Understand the effects of surface charge of the filter cartridge on fiber collection.

Respirator Filter

| Filter Code | Type                 | Manufacturer        | Solid Volume Fraction | Fiber Diameter (μm) |
|-------------|----------------------|---------------------|-----------------------|---------------------|
| A           | Disposable face mask | 3M (St. Paul, MN)   | 0.114                 | 3.89                |
| B           | Dust/fume/mist (N95) | MSA (Pittsburg, PA) | 0.044                 | 2.12                |
| C           | HEPA (N100)          | MSA (Pittsburg, PA) | 0.056                 | 0.51                |

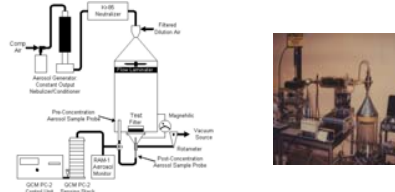


## Experimental Methods

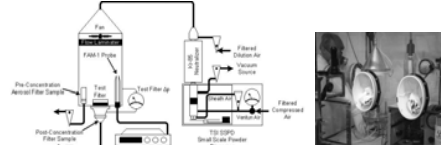
- Measure the surface charge potential of the filter cartridge with a field potential meter.
- Effects of high temperature and high humidity treatment on surface potential
- Measure the fiber penetration on filters using spherical particles as well as three asbestos fibers.
- Experimental parameters
  - Flow rate
  - Filter charge status

## Experimental Methods (Continued)

Experimental Setup (DOS Aerosol)

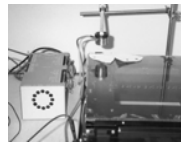


Experimental Setup (Fiber Aerosol)



Surface Potential Measurements

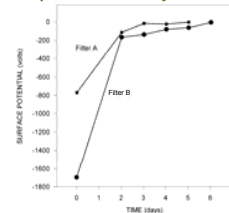
Electrostatic field meter



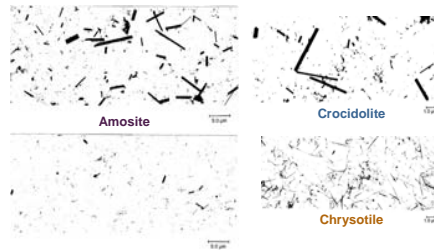
New filter

Filter treated at 38°C and >90% RH

Effects of Temperature/Humidity on Surface Potential



Fiber Aerosol Penetration



## Experimental Methods (Continued)

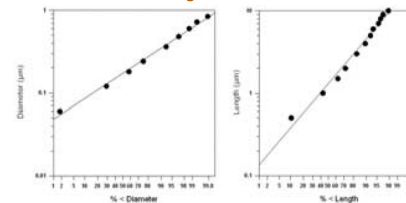
Fiber Counting



Fiber Counting  
Fiber Diameter (μm)

|             | 0.0 – 0.06 | 0.07 – 0.12 | 0.13 – 0.18 | 0.19 – 0.24 | 0.25 – 0.36 | 0.37 – 0.48 | 0.49 – 0.60 |
|-------------|------------|-------------|-------------|-------------|-------------|-------------|-------------|
| 0.0 – 0.5   | 10         | 66          | 20          | 0           | 0           | 0           | 0           |
| 0.51 – 1.00 | 8          | 50          | 53          | 19          | 7           | 0           | 0           |
| 1.01 – 2.00 | 2          | 19          | 26          | 16          | 12          | 6           | 0           |
| 2.01 – 3.0  | 0          | 6           | 4           | 5           | 2           | 2           | 0           |
| 3.01 – 5.0  | 0          | 3           | 1           | 2           | 2           | 1           | 0           |
| 5.01 – 6.0  | 0          | 0           | 0           | 0           | 1           | 0           | 0           |
| 6.01 – 7.0  | 0          | 0           | 0           | 0           | 0           | 0           | 0           |
| 7.01 – 8.0  | 0          | 0           | 0           | 0           | 0           | 0           | 0           |
| 8.01 – 9.0  | 0          | 0           | 0           | 0           | 0           | 0           | 0           |
| 9.01 – 10.0 | 0          | 0           | 0           | 0           | 0           | 0           | 0           |
| 10+         | 0          | 0           | 0           | 0           | 0           | 0           | 1           |

Fiber Diameter and Length  
Bivariate Lognormal Distribution

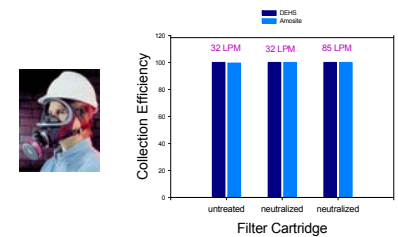


Fiber Size Distribution

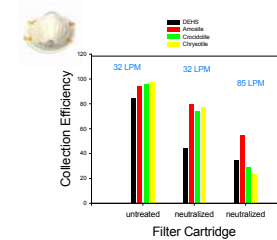
|             | CMD (μm)      | $\sigma_{gD}$ | CML (μm)    | $\sigma_{gL}$ |
|-------------|---------------|---------------|-------------|---------------|
| Amosite     | 0.18 ± 0.01   | 1.82 ± 0.11   | 1.19 ± 0.19 | 2.32 ± 0.14   |
| Crocidolite | 0.083 ± 0.015 | 1.79 ± 0.07   | 0.53 ± 0.05 | 1.68 ± 0.10   |
| Chrysotile  | 0.030 ± 0.004 | 1.33 ± 0.13   | 0.62 ± 0.12 | 2.15 ± 0.22   |

## Experimental Methods (Continued)

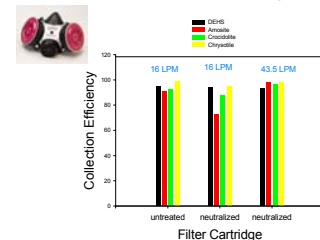
Total Collection Efficiency



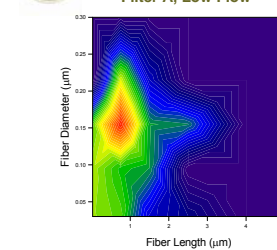
Total Collection Efficiency



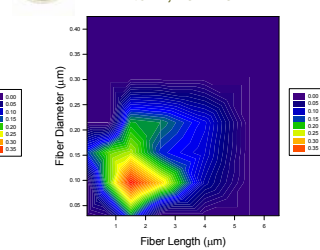
Total Collection Efficiency



Crocidolite Penetration  
Filter A, Low Flow



Amosite Penetration  
Filter A, Low Flow



## Conclusions

- Only respirators with a HEPA filter performed consistently on both spherical test aerosols and three asbestos fibers.
- The performances of the dust/mist filter and disposable face mask deteriorated when the charge potential on the filter was removed or as the flow rate changed.
- Surface charges decreased in a high-temperature, high-humidity environment and were neutralized within 1 week.
- We showed that fiber penetration depends on both diameter and length.





# “Toluene Adsorption on Activated Carbon Fibers: Implication on Respiratory Protection”

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University of Alabama at Birmingham



## Background

Granular activated carbon (GAC) is currently the standard adsorbent used in respiratory protection against volatile organic compounds (VOCs) and gases. However, GAC has some drawbacks, particularly its need for containment which adds to the weight and bulkiness of the respirator.

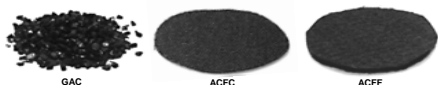
Activated carbon fiber (ACF) has been considered to be an alternate adsorbent for controlling VOCs that overcome some of the drawbacks of GAC. ACF has certain advantages over GAC such as its larger surface area, larger adsorption capacities and kinetics, and ease in handling due to its form and light weight.

## Statement of Purpose

The purpose of this study is to compare the critical bed depths and adsorption capacities of granular activated carbon (GAC) with activated carbon fibers (ACFs) of different forms and surface areas.

## Materials & Methods

Seven (7) types of adsorbents were analyzed: GAC, 3 ACF cloth (ACFC) and 3 ACF felt (ACFF). Each ACF forms have 3 different manufacturer-specified surface areas of 1000, 1500 and 1800 or 2000 m<sup>2</sup>/g. The adsorbents were treated in an oven at 200 °C overnight prior to testing.



The materials were challenged in a stainless steel sample chamber with a constant concentration of toluene at 500 ppm, at constant air temperature (23°C), relative humidity (50%) and air flow (3 LPM) at 4 different adsorbent bed depths and mass. Breakthrough data were obtained for each adsorbent using gas chromatography with flame ionization detector (Agilent 6850®).



The surface areas of each adsorbent were determined by an automatic physisorption analyzer (Micromeritics ASAP 2020®) using high purity nitrogen (99.99%) at 77 K.

## Data Analysis

**Critical Bed Depth:** For each adsorbent type, the time at 10% breakthrough was plotted against the adsorbent bed depths. The bed depth (X) at which 10% BT (Y) = 0 is the critical bed depth for the specific adsorbent.

**Adsorption Capacity:** For each adsorbent type, the time at 50% breakthrough is plotted against the adsorbent mass, creating a linear regression line ( $t_b = a(W) + b$ ) that is used with the Wheeler equation (shown below) to derive the equation to calculate adsorption capacity,  $W_e$ .

Wherein:

$t_b$  – breakthrough time (min)

$C_e$  – exit concentration (g/cm<sup>3</sup>)

$C_0$  – inlet concentration (g/cm<sup>3</sup>)

$Q_e$  – volumetric flow rate (cm<sup>3</sup>/min)

$W$  – weight of adsorbent (g)

$\rho_b$  – bulk density of packed bed (g/cm<sup>3</sup>)

$k_a$  – first order rate constant of adsorption (min<sup>-1</sup>)

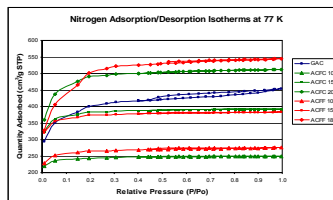
$W_e$  – kinetic adsorption capacity (g/g)

$$t_b = \frac{W_e}{C_0 Q_e} \left[ W - \frac{\rho_b Q_e}{k_a} \ln \left( \frac{C_0}{C_e} \right) \right]$$

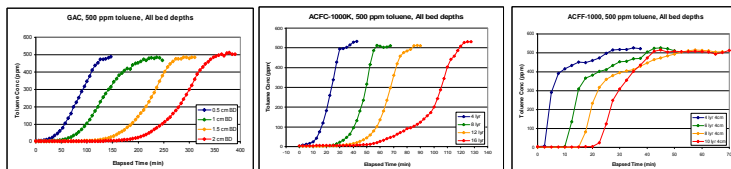
## Results

- The measured surface area of the adsorbents are greater than the manufacturer-specified surface area (table 1).
- The adsorption/desorption isotherms of nitrogen for the 7 adsorbent types using an automatic physisorption analyzer are shown in the graph below.

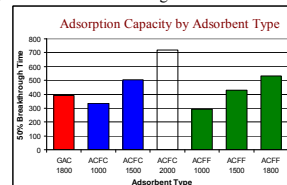
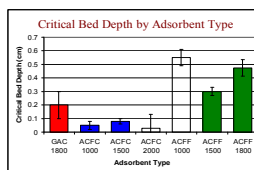
| Table 1. Surface Area by Adsorbent Type |                                  |                   |
|-----------------------------------------|----------------------------------|-------------------|
| Adsorbent                               | Surface Area (m <sup>2</sup> /g) |                   |
|                                         | Manufacturer Specified           | Measured (x ± SD) |
| GAC                                     | ---                              | 1835 ± 18         |
| ACFC 1000                               | 1000                             | 1077 ± 3          |
| ACFC 1500                               | 1500                             | 1693 ± 5          |
| ACFC 2000                               | 2000                             | 2202 ± 12         |
| ACFF 1000                               | 1000                             | 1173 ± 4          |
| ACFF 1500                               | 1500                             | 1650 ± 5          |
| ACFF 1800                               | 1800                             | 2342 ± 36         |



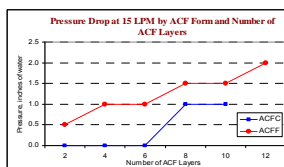
- The graph below shows sample breakthrough curves of toluene for GAC, ACFC and ACFF.



- The critical bed depth of GAC is 275% higher than the average of ACFC but is 55% lower than the average of ACFF.
- The ACFC has a lower critical bed depth compared to that of the ACFF.
- The critical bed depths of ACF cloth is 73 – 94% lower than those of the ACF felt when similar surface areas of each form are compared. On the average, critical bed depth of ACF cloth is 88% lower than that of the ACF felt.
- The adsorption capacity of GAC is 25% higher than the average of both ACF types with a surface area of 1000 m<sup>2</sup>/g but is 28% lower than the average adsorption capacity for the rest of ACF with surface area of 1500 m<sup>2</sup>/g or more.
- The adsorption capacities of ACF cloth is 14 – 35% higher than those of the ACF felt when similar surface areas of each form are compared. On the average, the adsorption capacity of ACF cloth is 24% higher than that of the ACF felt.



- At an air flow of 15 LPM, the pressure drop across both the ACFC and ACFF is less than 1.5 inches of water for 10 ACF layers or less.



## Discussion

### Breakthrough

- The breakthrough curves show unique shapes for each type of adsorbent.
- GAC: The breakthrough of toluene occurs slowly as shown by the gradual increase in concentration at the start of breakthrough and as complete breakthrough was reached.
- ACF cloth: The increase in toluene concentration occurs slowly at the start of breakthrough curves. Such gradual increase is more prominent as the number of adsorbent layers increase.
- ACF felt: The increase in toluene concentration occurs abruptly from the time the breakthrough starts. However, the concentration increase slows down at 100% breakthrough is reached, particularly for the least number of adsorbent layers.

### Critical Bed Depth

- Critical bed depth is defined as the minimum bed depth of the adsorbent required to reduce the concentration of toluene by 90%.
- All the ACF cloth samples have lower critical bed depths compared to the GAC.
- The ACF cloth has a lower critical bed depth compared to that of the ACF felt. This makes sense because the ACF cloth layer is thinner and denser than the ACF felt layer, which is more spongy.
- Based on the critical bed depth, the ACF cloth with the highest surface area of 2000 m<sup>2</sup>/g is the best adsorbent because it has the smallest critical bed depth.

### Adsorption Capacity

- Adsorption capacity is the maximum amount of substance adsorbed by a material.
- The higher the adsorption capacity, the better the adsorbent because it adsorbs more chemicals with the same amount of material.
- The adsorption capacity of GAC is higher than the average of both ACF types with the lowest surface area (ACFC and ACFF 1000) because the surface area of GAC, which is 1800 m<sup>2</sup>/g, is much higher.
- However, average adsorption capacity of the rest of ACF with surface area of 1500 m<sup>2</sup>/g or more is higher than that of the GAC. It is important to note that the ACF with a lower surface area of 1500 m<sup>2</sup>/g compared to that of the GAC, has a higher adsorption capacity compared to GAC.
- Based on the adsorption capacity, ACF cloth with the highest SA is the best adsorbent because it has the highest adsorption capacity.

### Pressure Drop

- The maximum allowable pressure drop requirement for chemical cartridge respirator, according to NIOSH, is 1.5 in H<sub>2</sub>O (40 mm H<sub>2</sub>O) for gases and/or vapors.
- For both the ACFC and ACFF, a maximum number of 10 layers may be used for respiratory protection at tested conditions.

## Conclusions

- Activated carbon fiber (ACF), in both cloth and felt forms, with higher surface areas have higher adsorption capacities, compared to the granular activated carbon (GAC).
- Specifically, the ACF cloth with higher surface area (1500 m<sup>2</sup>/g or more) has the smallest critical bed depth and highest adsorption capacity for this challenge concentration (500 ppm toluene), which makes it a good adsorbent for thinner and lighter respirators.
- Given its advantages over GAC, ACF shows promise in the development of disposable respirators or masks for short-term protection against toluene, and probably similar volatile organic compounds (VOCs).

## Acknowledgements

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# Comparison of Nanoparticle Filtration Performance of NIOSH-approved and CE Marked Filtering Facepiece Respirators

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<sup>1</sup> NIOSH - National Personal Protective Technology Laboratory, Pittsburgh, PA, <sup>2</sup> EG&G Technical Services, Inc., Pittsburgh, PA

## Introduction

- The National Institute for Occupational Safety and Health (NIOSH) and European Norm (EN) (CE marked) certifications of filtering facepiece respirators (FFRs) employ different test protocols and have slightly different filtration performance requirements
- NIOSH:
  - N95 FFRs - charge neutralized polydisperse NaCl aerosol at 85 L/min flow rate
  - P100 FFRs - charge neutralized polydisperse dioctyl phthalate aerosol at 85 L/min flow rate
- CE marked FFP2 and FFP3 FFRs - Non-neutralized polydisperse NaCl and paraffin oil aerosols at 95 L/min flow rate
- Filtration efficiency: N95 - 95%, P100 - 99.97%, FFP2 - 94%, FFP3 - 99%
- Comparative filtration performance of NIOSH-approved and CE marked European FFRs is lacking
- Filtration performance of NIOSH-approved and CE marked FFRs for a wide range of nanoparticles is lacking

## Objectives

- To compare the filtration performance of NIOSH-approved and CE marked FFRs using testing methods consisting of polydisperse and monodisperse aerosol particles
- To study the filtration performance of NIOSH-approved and CE marked FFRs over a wide range of monodisperse particles (4-1000 nm), including nanoparticles (< 100 nm)
- To assess electrostatic capturing of particles by NIOSH-approved and CE marked FFRs

## Methods

- Three test methods were used in this study:
  - Polydisperse Aerosol Test (PAT) - TSI 8130
    - CMD 75nm
    - GSD < 1.86
    - Nebulizer Generated NaCl particles
  - Monodisperse Aerosol Test (MAT 1) - TSI 3160
    - Size range: 20-400nm
    - Nebulizer Generated NaCl Particles
  - Monodisperse Aerosol Test 2 (MAT 2) - NIOSH
    - Size range: 4-30nm
    - Ag particles generated by evaporation/condensation method
- Initial penetration levels were measured before and after isopropanol (IP) treatment of FFRs using neutralized particles at 85 L/min flow rate
- IP treatment: FFRs were dipped in liquid isopropanol, removed, and dried overnight

## Results

Table 1. Polydisperse aerosol penetration levels for the different FFR types.

| Respirator Type      | N95   |       | FFP2  |       | P100  |       | FFP3  |       |
|----------------------|-------|-------|-------|-------|-------|-------|-------|-------|
|                      | M1    | M2    | M1    | M2    | M1    | M2    | M1    | M1    |
| Mean Penetration (%) | 0.565 | 0.703 | 0.505 | 0.270 | 0.003 | 0.022 | 0.009 | 0.014 |
| Standard Deviation   | 0.527 | 0.200 | 0.275 | 0.096 | 0.002 | 0.003 | 0.004 | 0.011 |

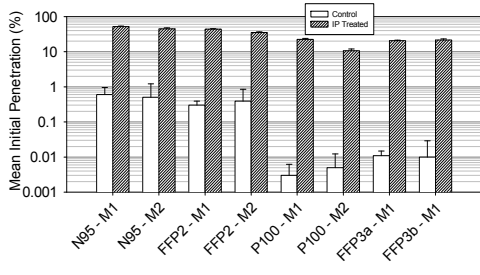


Fig 1. Penetration levels for PAT at 85 L/min for control and isopropanol treated FFRs. Error bar indicates 95% confidence interval.

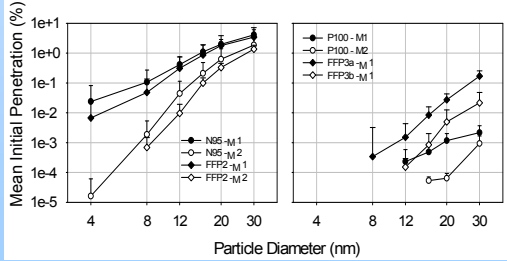


Fig 2. Penetration levels for monodisperse silver particles (4-30 nm) for N95, FFP2, P100 and FFP3 respirators at 85 L/min flow rate.

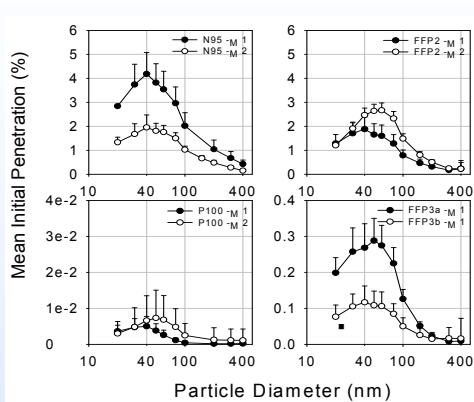


Fig 3. Penetration levels of monodisperse NaCl particles (20-400nm) for control N95, FFP2, P100 and FFP3 respirators at 85 L/min.

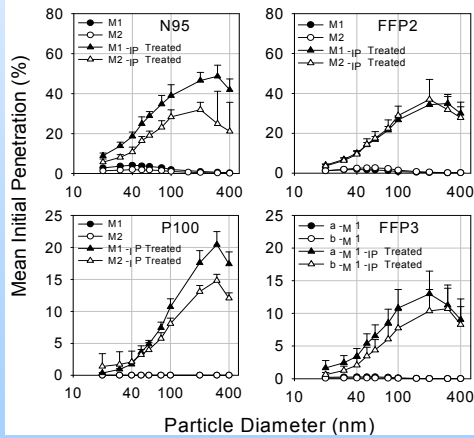


Fig 4. Penetration levels of monodisperse NaCl particles (20-400 nm) for control and isopropanol treated N95, FFP2, P100 and FFP3 respirators at 85 L/min flow rate.

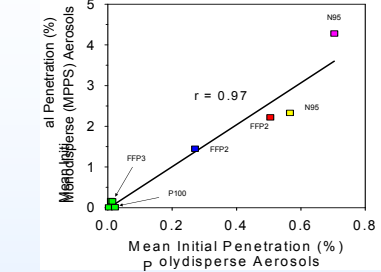


Fig 5. Correlation of monodisperse (MPPS) and polydisperse NaCl aerosol penetrations for N95, FFP2, P100 and FFP3 respirators at 85 L/min flow rate.

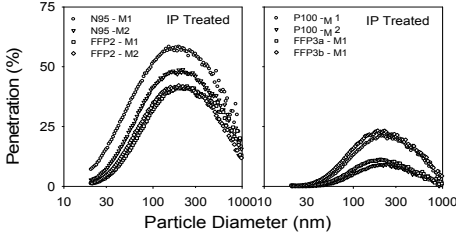


Fig 6. Penetration levels of IP treated FFR's from SMPS scan data (20-1000nm).

## Conclusions

- Particle penetration results obtained in this study confirmed that NIOSH-approved and CE marked FFRs provide filtration performance expected of them across a wide range of particle sizes, including nanoparticles
- Particle penetration decreased with decreasing particle size from 30 nm down to 4 nm as predicted by single-fiber filtration theory
- Most Penetrating Particle Size (MPPS) was in the 30-50 nm for all tested FFRs, similar to other electret filters
- Particle penetration levels for NIOSH-approved and CE marked FFRs were comparable
  - N95's were comparable to FFP2's
  - P100's were comparable to FFP3's
- Isopropanol treatment confirmed that all of the FFRs in the study contained electret filter media

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# Powered Air-Purifying Respirator (PAPR) Program

Richard J. Vojtko

## Goal

Develop new performance requirements for the PAPR and promulgate them as regulations into 42 CFR Part 84 to include the following:

- Criteria based on latest credible human physiological factor limits and ergonomics
- Requirements that allow emerging and future technologies and innovative designs to be tested and approved
- Ensure NIOSH certification requirement provides workers with safe, protective PAPR
- Incorporate into Standard Test Procedures (STP) the required use of test equipment that employs state of the art technology to test performance requirements
- Include provision for enhanced protection through optional enhanced requirements including chemical, biological, radiological and nuclear (CBRN) protection, lower level CBRN (LCBRN), flammability and heat resistance, silent operation, operational temperature range, hydration device, and intrinsic safety



## Partners

U.S. Army RDECOM, Respirator Manufacturers, and OSHA

## Stakeholders

OSHA, Respirator manufacturers, Employers, Labor unions, Respirator users and Healthcare providers



## Summary of Conceptual Changes, PAPR, Subpart P

|                                                              |                                                                                                                                                                                 |
|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Work Rates -                                                 | Approval available for low, moderate and high work rates                                                                                                                        |
| Positive Pressure -                                          | PAPRs may be required to operate at positive pressure when tested with a breathing machine at the respiration rate corresponding to the work rate specified by the manufacturer |
| Gas/Vapor Service Life Tests -                               | Challenge gas flow based on selected work rate, test concentrations and time based on uniform test rationale                                                                    |
| Particulate Testing -                                        | PAPR 95 and PAPR 100 approval based on dioctyl phthalate (DOP) testing. No silica dust loading test                                                                             |
| Power Monitor -                                              | Indicator to monitor power source and status and provide 15-minute alarm. 15-minute escape battery required for externally powered PAPRs                                        |
| Eye/Lens Requirements -                                      | Requirements for visual field, optical quality, fogging and impact resistance                                                                                                   |
| End of Service Life (ESLI) Indicator -                       | Criteria for those PAPRs utilizing cartridges or canisters with ESLI                                                                                                            |
| Failure Mode and Effects Analysis (FMEA) -                   | Manufacturer requirements                                                                                                                                                       |
| Fit Test -                                                   | Replace qualitative isoamyl acetate (IAA) test with quantitative laboratory respiratory protection level (LRPL) test                                                            |
| Carbon Dioxide (CO <sub>2</sub> ) Machine Test -             | Provide non-human screening of PAPRs to determine CO <sub>2</sub> retention in breathing zone                                                                                   |
| CO <sub>2</sub> and oxygen (O <sub>2</sub> ) Human Testing - | Determine practical performance for these two key items                                                                                                                         |
| CBRN and LCBRN -                                             | Incorporate the previously approved Statement of Standard for CBRN PAPR as an enhanced requirement of the general PAPR standard                                                 |
| Optional Silent Mode for Tight Fitting CBRN PAPR -           | Allows first responders and law enforcement personnel to eliminate blower noise to either detect other sounds or provide a greater degree of stealth                            |
| Intrinsic Safety -                                           | Respirator manufacturer provides appropriate information from an accredited approval authority                                                                                  |

## Method to Codify Performance Requirements into 42 CFR Part 84

1. Complete PAPR criteria and standard test procedures for certification
2. Complete the preamble and comply with all federal requirements
3. Submit to the Federal Register "Notice of Proposed Rulemaking"
4. Hold additional public meetings as information exchange meetings
5. Open a docket to provide supporting information for public access/comment: Rulemaking records including submitted comments, scientific reports, test data and related information
6. Publish a final rule in the Federal Register
  - Contains all regulatory text
  - Includes responses to public meeting and docket comments
  - Explains changes from the proposed rule to the final rule and the rationale

## Milestones

|        |                                             |
|--------|---------------------------------------------|
| 4QFY09 | Finalize preamble; supporting documentation |
| 1QFY10 | Initiate rulemaking activities              |

## Expected Outputs

- Elimination of obsolete requirements
- Update STPs and Standard Operating Procedures (SOPs) for current, new, and CBRN requirements
- Greater variety of PAPR designs
- Final rule stated in 42 CFR Part 84, Subpart P
- CBRN certified PAPRs

## Expected Outcomes

- Improve PAPR performance for general industrial workers, healthcare providers and emergency responders
- Enhanced protection from CBRN PAPRs

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# Supplied-Air Respirator (SAR) Program

Jeffrey D. Palcic  
NIOSH/NPPTL

## Goal

**Develop new performance requirements for the SAR and promulgate them as regulations into 42 CFR Part 84 to include the following:**

- Revise and update minimum requirements used to determine the effectiveness of SAR during entry into and escape from atmospheres not Immediately Dangerous to Life or Health (non-IDLH)
- Criteria based on latest credible human physiological factor limits and ergonomics
- Requirements that allow emerging and future technologies and innovative designs to be tested and approved
- Ensure that NIOSH certification requirement provides workers with safe, protective SAR
- Incorporate into the standard test procedures (STP) the required use of test equipment that employs state of the art technology to test the performance requirements
- Develop minimum requirements to determine the effectiveness of combination SAR/self-contained breathing apparatus (SCBA) used for escape from chemical, biological, radiological, and nuclear (CBRN) (optional requirements) atmospheres that are Immediately Dangerous to Life or Health (IDLH)



## Partners

U.S. Army RDECOM, Respirator Manufacturers, and OSHA

## Stakeholders

OSHA, Respirator Manufacturers, Employers, Labor Unions, Respirator Users



## Summary of Conceptual Changes, SAR, Subpart J

|                                              |                                                                               |                                                       |
|----------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------|
| Description –                                | Eliminate Type A, AE, B, BE, re-designate C and CE as "Airline",              | and add "Airsourse Type" i.e. blower, air compressor  |
| Eye Piece – and                              | Updated references and added visual field score, haze, luminous communication | transmittance, abrasion, low temperature/fogging,     |
| Airsourse Requirements – minimum performance | Carbon monoxide (CO) concentration, air temperature, air supply               | volume, filtration and blower/air compressor          |
| Airline Requirements –                       | Continuous flow, demand and pressure demand, and                              | performance tests                                     |
| Air Supply Lines –                           | Requirements for Airline and Airsource respirators will be                    | described in 42 CFR Part 84, Subpart J, Table 1       |
| Hose Permeation –                            | Same test protocol for gasoline, but permeation tests using                   | kerosene and toluene have been added                  |
| Harness Pull Test – heavier                  | Revised for Airline and Airsource respirators. Pull criteria                  | increased due to fact that people are bigger and      |
| Airflow Resistance –                         | Combined into one section with criteria for each type of Airline              | and Airsource respirator                              |
| Exhalation Valve Leakage –                   | Same test protocol with more stringent criteria                               |                                                       |
| Power Tool Take-Off – of two                 | New concept standard will allow for a pneumatic tool take-off                 | to ease user problems encountered with present use    |
| Fit Test – test                              | airlines                                                                      | quantifiable factors of current Isoamyl Acetate (IAA) |
| CO <sub>2</sub> Requirement –                | Use of total inward leakage (TIL) test to eliminate non-                      |                                                       |
| Combination Unit –                           | CO <sub>2</sub> test is needed based on NIOSH research                        | data                                                  |
| CBRN – combination                           | Provides for Airline SAR/SCBA which incorporate an escape                     | bottle                                                |
|                                              | Criteria which have been established for CBRN SCBA                            | respirators are candidate standards for specific      |
|                                              | CBRN SAR                                                                      |                                                       |

## Method to Codify Performance Requirements into 42 CFR Part 84

1. Complete SAR criteria and standard test procedures for certification
2. Complete the preamble and comply with all federal requirements
3. Submit to the Federal Register "Notice of Proposed Rulemaking"
4. Hold additional public meetings as information exchange forums
5. Open a docket to provide supporting information for public access/comment: Rulemaking records including submitted comments, scientific reports, test data and related information
6. Publish a final rule in the Federal Register
  - Contains all regulatory text
  - Includes responses to public meetings and docket comments
  - Explains changes from the proposed rule to the final rule and the rationale

## Milestones

|           |                        |
|-----------|------------------------|
| May 2009  | Post new Concept Paper |
| Sept 2009 | Public Meeting         |

## Expected Outputs

- Update requirements to align with current technology
- Update STPs and standard operating procedures (SOP) for current, new, and CBRN requirements
- Facilitate development of a greater variety of SAR designs
- CBRN Certified SAR
- Publish final rule modifying 42 CFR Part 84, Subpart J

## Expected Outcomes

- Improve SAR performance for general industrial workers, and emergency responders
- Availability of SAR for use in CBRN environments

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# Concept for NIOSH Certification of Air-Fed Ensembles

Colleen S. Miller  
NIOSH/NPPTL

## Goal

Develop an update to 42 CFR Part 84 to address technology where the ensemble acts as the respirator

- Review current nationally and internationally recognized standards addressing the performance of suits and ensembles that provide integrated respiratory protection
- Identify current and potential job classifications whose tasks require this type of respiratory and dermal protection
- Further develop the NIOSH concept for certification of Air-fed ensembles, allow latest technology and innovative designs to be tested and have sufficient flexibility to accommodate future technologies
- Ensure that NIOSH certification requirements provide workers with safe, protective ensembles that act as respirators
- Develop and document standard test procedures (STP) and the required use of test equipment that employs state of the art technology to evaluate performance requirements identified in the concept

## Partners

Ensemble Manufacturers and Users, NASA, DOE, OSHA, ASTM

## Stakeholders

OSHA, Ensemble Manufacturers, Employers, Labor Unions, Respirator Users including the DOE, CDC, US Army, Paint, Petrochemical and Pharmaceutical Industries, ASTM



## Milestones

May 2009 Post initial concept requirements on NIOSH website

Sept 2009 Public meeting to discuss the concept

## Current Development Plan Status

The Air-Fed Ensemble Development Plan was presented to the public in December 2008

The following test descriptions outline requirements, most relating to respiratory protection, that are included in a majority of the air-fed protective ensemble specification standards or drafts of standards.

| Test description                                 | ISO | NASA | DOE | ANSI | CEN |
|--------------------------------------------------|-----|------|-----|------|-----|
| Inward leakage, aerosol penetration              | ▲   | ▲    | ▲   | ▲    | ▲   |
| Couplings                                        | ▲   | ▲    | ▲   | ▲    | ▲   |
| Air flow rate (general)                          | ▲   | ▲    | ▲   | ▲    | ▲   |
| Air-supply lines                                 | ▲   | ▲    | ▲   | ▲    | ▲   |
| Air-supply source                                | ▲   | ▲    |     | ▲    | ▲   |
| Breathing resistance                             | ▲   | ▲    |     | ▲    | ▲   |
| Breathing tube/hose                              | ▲   | ▲    |     | ▲    | ▲   |
| Carbon dioxide content of inhalation air         | ▲   | ▲    | ▲   | ▲    | ▲   |
| Compressed air supply tube                       | ▲   | ▲    |     | ▲    | ▲   |
| Conditioning by temperature and/or wearing       | ▲   | ▲    |     | ▲    | ▲   |
| Connections (general, for cleaning)              | ▲   | ▲    |     | ▲    | ▲   |
| Connection strength                              | ▲   | ▲    | ▲   |      | ▲   |
| Continuous flow valve                            | ▲   | ▲    |     | ▲    | ▲   |
| Exhaust assemblage                               | ▲   | ▲    |     | ▲    | ▲   |
| External breathing hose strength                 | ▲   | ▲    | ▲   | ▲    | ▲   |
| External breathing hose (resistance to collapse) | ▲   | ▲    | ▲   | ▲    | ▲   |
| Internal breathing hose (strength)               | ▲   | ▲    |     | ▲    | ▲   |
| Internal breathing hose (resistance to collapse) | ▲   | ▲    |     | ▲    | ▲   |
| Noise                                            | ▲   | ▲    | ▲   | ▲    | ▲   |
| Pressure in suit                                 | ▲   | ▲    |     | ▲    | ▲   |
| Resistance to ignition                           |     |      |     | ▲    | ▲   |
| Resistance to flame                              | ▲   | ▲    | ▲   | ▲    |     |
| Vision/visor                                     | ▲   | ▲    |     | ▲    | ▲   |
| Warning and measuring means                      | ▲   | ▲    |     | ▲    | ▲   |

The following test descriptions outline requirements that may not be included in a majority of the standards reviewed, but are considered important to include due to proposed updates to SAR and PAPR subparts and the intended use of the ensembles.

| Test description                 | ISO | NASA | DOE | ANSI | CEN |
|----------------------------------|-----|------|-----|------|-----|
| Air-supply harness               |     | ▲    |     | ▲    |     |
| Air-supply system pressure       |     |      |     | ▲    |     |
| Escape test, doffing             |     | ▲    | ▲   |      |     |
| Remaining service life indicator |     | ▲    |     |      |     |
| Test temperature                 | ▲   | ▲    |     | ▲    |     |
| Unmanned CO <sub>2</sub>         |     | ▲    |     |      |     |
| Weight requirement               |     | ▲    |     |      |     |

## Expected Outputs

Develop requirements to align with current technology and user environments

Develop standard test procedures (STP) and standard operating procedures (SOP) for new, and current requirements, when applicable

Publish final rule in 42 CFR Part 84

## Expected Outcomes

Improved ensemble performance for radiological workers, biological, chemical, petrochemical, and pharmaceutical industry workers, and high performance paint applicators

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# Development of Computer-Aided Face-Fit Evaluation Methods

Ziqing Zhuang<sup>1</sup>, Dennis Viscusi<sup>1</sup>, Stacey Benson<sup>2</sup>, and Ronald Shaffer<sup>1</sup>

<sup>1</sup>NIOSH/NPPTL, Pittsburgh, PA, <sup>2</sup>EG&G Technical Services, Pittsburgh, PA

## Project Goals

- Establish an anthropometric database of the face and size distribution of respirator users
- Analyze facial dimension differences among gender, race, age and occupation groups
- Develop a series of headforms to be incorporated into standards and aid respirator design
- Use 3-D Geometric Morphometric techniques to investigate facial shape and size variation

## Stakeholders/Partnerships

- OSHA
- MSHA
- Respirator wearers
- SDOs
- Respirator manufacturers

## Background

- A US anthropometric survey was conducted in 2003 and a Chinese survey in 2006
- 3997 subjects were measured and 1039 scanned in the US survey
- NIOSH bivariate and principal component analysis (PCA) fit test panels were developed

## Key Findings to Date

- The Los Alamos National Laboratory (LANL) full-facepiece panel excluded > 15% of the current US workforce
- Face length and face width are appropriate dimensions for the development of respirator fit test panels
- The NIOSH bivariate fit test panel and the principal component analysis (PCA) fit test panel are more representative than the LANL panel and cover 97.7% and 95% of the field survey subjects, respectively
- The NIOSH panels (bivariate and PCA) cover over 96% and 95% of the Chinese study subjects, respectively
- Fit test panels representative of the Chinese civilian workforce were created (Figure 1A and 1B)

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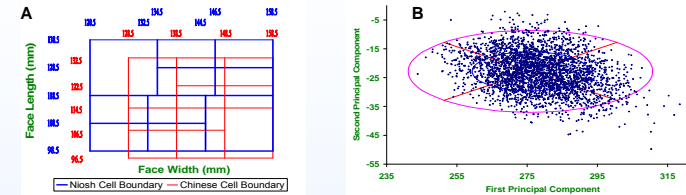


Figure 1. A) Boundary comparison of the NIOSH and Chinese bivariate panels and B) Chinese PCA panel

## Current Research

- Use PCA and regression analysis to explore differences among race, age, gender (Figure 2A), and occupation (Figure 2B) in facial measurements for the U.S. workforce
- Develop five test headforms representative of the current U.S. workforce (Figures 3 and 4) by using Polyworks software to process and average 3-D scans of five subjects for each face size category based on the PCA panel
- Evaluate the appropriateness of NIOSH panels for consensus respiratory protective device standards (Figure 5)
- Conduct Geometric Morphometrics analyses using 3-D coordinates for all landmarks

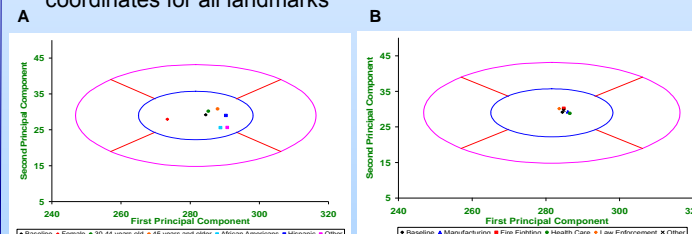


Figure 2. Face size and shape as a function of A) race, age, gender and B) occupation

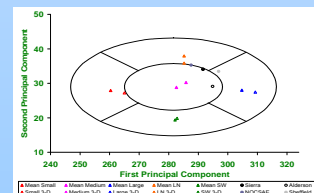


Figure 3. Distribution of the newly constructed headforms (labeling 3-D in the legend), computed mean of the traditional manual measurements, and four current standard headforms

## Current Research (con't)



Figure 4. Small, medium, large, long/narrow and short/wide 3-D digital headforms

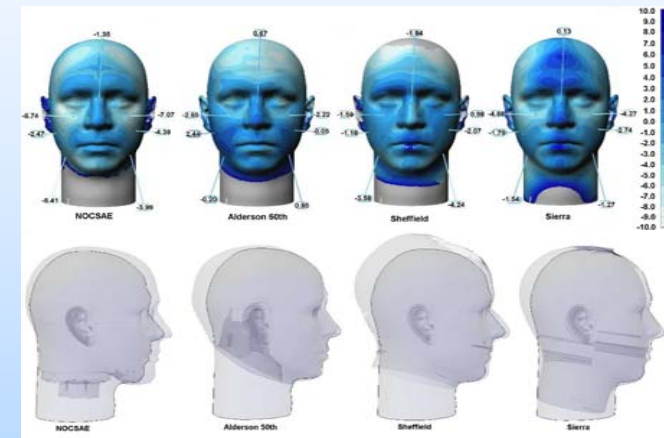


Figure 5. Comparison of the NIOSH medium headform with four current standard headforms

## Key Publications

- Zhuang Z and Bradtmiller B [2005]. Head-and-Face Anthropometric Survey of U.S. Respirator Users. J. Occup and Environ Hyg, 2, 567-577.
- Roberge J, Zhuang Z, and Stein L [2006]. Association of body mass index with facial dimensions for defining respirator fit test panels. Journal of the International Society for Respiratory Protection, 23(1-II):44-52.
- Zhuang Z, Bradtmiller B, and Shaffer R [2007]. New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. J. Occup and Environ. Hyg. 4, 647-659.
- Du L, Zhuang Z, Guan H, et al [2008]. Head-and-Face anthropometric survey of Chinese workers. Ann. Occup. Hyg., 52: 773-782.
- Chen W, Zhuang Z, Benson S, et al. New respirator fit test panels representing the current Chinese civilian workforce. Ann. Occup. Hyg., [in press].

# Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering-Facepiece Respirator Fit

Ziqing Zhuang<sup>1</sup>, Stacey Benson<sup>2</sup>, and Dennis Viscusi<sup>1</sup>, <sup>1</sup>NIOSH/NPPTL, Pittsburgh, PA, <sup>2</sup>EG&G Technical Services, Pittsburgh, PA

## Project Goals

- The specific aims of this project are to:
  - Assess the rate at which respirator fit changes as a function of time for a representative sample of subjects wearing filtering-facepiece respirators (FFR)
  - Investigate the factors that affect such change

## Stakeholders/Partnerships

- OSHA, ISO, MSHA
- Respirator wearers
- Respirator manufacturers

## Background

- No scientific studies have been done tracking respirator fit on individuals over time
- Observations from four companies were considered in establishing OSHA annual fit test standard, i.e. 29 CFR 1910.134
  - Texas Chemical Council: virtually no individuals fail fit tests a year after initial test
  - Exxon Company: < 1% annual fit test failure rate
  - Lord Corporation: < 1-3% annual fit test failure rate
  - Hoffmann-La Roche: 7% switch to different sizes and/or models after 2 years
- Currently, there is no scientific study quantifying the benefit of annual fit testing

## Methods

- A total of 220 subjects will be recruited for this study according to each face size category of the NIOSH respirator fit test panel (Figure 1)
- Subjects will be properly fitted with an FFR and trained in proper donning and doffing techniques
  - Obtain a fit factor  $\geq 100$  for one of the first three fit tests consisting of 5 exercises
  - Obtain 90<sup>th</sup> percentile total inward leakage < 0.05 for nine donnings
- Once assigned, subjects will wear the same style and size of the FFR (Figure 2) for the subsequent testing

|                  | Face Width (mm) |       |       |        |
|------------------|-----------------|-------|-------|--------|
|                  | 120.5           | 134.5 | 146.5 | 158.5  |
| Face Length (mm) | 138.5           |       | 9 (2) | 10 (2) |
|                  | 128.5           | 6 (2) | 7 (4) | 8 (2)  |
|                  | 118.5           |       |       |        |
|                  | 108.5           | 3 (2) | 4 (5) | 5 (2)  |
|                  | 98.5            | 1 (2) | 2 (2) |        |

Figure 1. NIOSH 25-member bivariate panel for testing respirators

## Methods Con't

- Facial anthropometric data will be collected using traditional methods and 3-D scanning (Figure 3, A)
- Subject characteristics, e.g., age, weight, height, dental status will also be collected
- Every six months the same measurements will be obtained
  - Facial anthropometric data
  - Quantitative fit test data for nine donnings
  - Subject Characteristics
- Changes in the following measurements/parameters will be analyzed for all subjects to assess correlations and other associations for time intervals of 6, 12, 18, 24, 30, and 36 months
  - Total inward leakage
  - Respirator fit
  - Facial dimensions
  - Subject Characteristics, e.g., age, weight, dental status
- Polyworks will be used to investigate how face size changes over time (Figure 3, B)



Figure 2. Styles of N95 Filter Facepiece Respirators (FFR)s

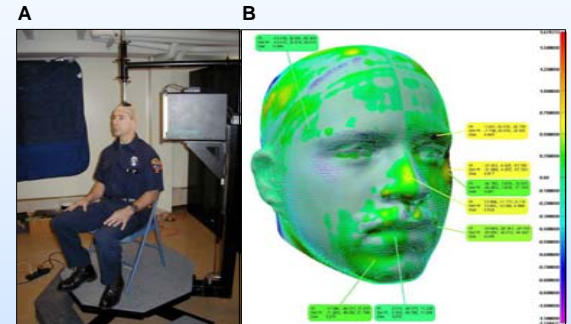


Figure 3. A) Individual being scanned with the Cyberware Rapid 3D Digitizer; B) Comparison of two faces showing gaps of 0 mm to less than 2 mm between the two faces

## Program Timelines

- FY07: Complete peer-review
- FY08: Obtain HSRB approval
- FY09: Begin experimental studies
- FY11: Complete experimental studies
- FY12: Produce final reports and guidance documents

## Expected Outcomes

- Quantify the extent that FFR fit changes over time
- Identify causal factors associated with changes in FFR fit
- Provide design criteria to help respirator manufacturers design better respirators
- Improve test methods and performance requirements for respiratory protection used by national and international standards development organizations

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# Leading the Way

## Personal Protective Equipment (PPE) and Safety Research at the University of Cincinnati Education Research Center

College of Engineering



College of Medicine



College of Nursing



Set-up of respiratory cartridges to test and evaluate the individual's ability to perform user seal checks

Evaluation of respiratory protection equipment in a water-damaged building in New Orleans



Evaluating the performance of respirators to protect against bioaerosol exposure



Examination of the role handrails play in preventing slip-related falls among older workers while walking on ramps in sub-optimal environmental conditions

Before



After



Nursing and Engineering re-design an ambulance stretcher to reduce lifting weight and potential for hand and finger injury.



Student project to characterize and reduce the noise level of a power tool



Set-up for vibration measurement

Set-up for noise measurement

For more information contact:

[erccoer@uc.edu](mailto:erccoer@uc.edu)



## Introduction

- Approximately 3 million farm workers
- High bioaerosol exposure is common
- Bioaerosols comprise diverse group of particles, cover wide size range
  - Bacteria, fungal spores, pollen and cell wall components, such as (1-3)- $\beta$ -D-glucan and endotoxin
  - Related to various adverse health effects
- Workplace Protection Factors (WPF) for bioaerosols in pilot study were lower than current OSHA Assigned Protection Factor.
- Penetration through filter vs. face seal leakage not known

## Methods

### Field experiment

- 13 human subjects on three different agricultural farms
  - Horse farm, swine confinement and corn farm
  - Medical clearance and fit-test before WPF testing
- Personal sampling set-up developed earlier ( Fig. 1A)
  - Two identical sampling lines
  - Sampling chamber, filter, OPC, and pump
- Respirators: N95 elastomeric (ER) and N95 filtering facepiece (FFR)

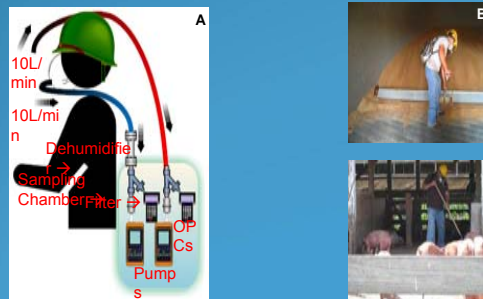


Figure 1. Personal sampling system (A) (Lee et al., Ann Occ. Hyg 49:245-257, 2005) and examples of field sampling (B)

### Laboratory experiment

- Manikin based experiment (Fig. 2)
- Penetration through filter media (completely sealed respirator) and face seal leakage (partially sealed respirator)
- Sinusoidal breathing pattern created by breathing simulator (Koken Ltd, Japan)
- Mean Inspiratory Flow Rate (MIF) 15, 30 and 85 L/min

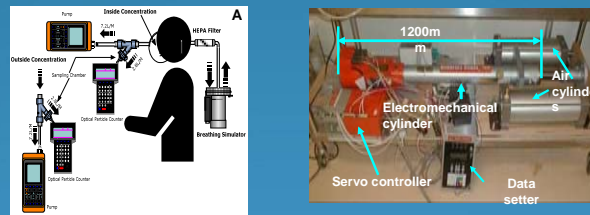


Figure 2. Experimental set-up for manikin-based testing (A) and a breathing simulator (B)

### Preliminary results

Table 1. WPFs against different types of particles in field study

| Particle type             | WPF for ER |     |      | WPF for FFR |     |      | Paired t-Test<br>p two tail |
|---------------------------|------------|-----|------|-------------|-----|------|-----------------------------|
|                           | N          | GM  | GSD  | N           | GM  | GSD  |                             |
| Total number of particles | 13         | 343 | 3.4  | 12          | 159 | 2.6  | 0.128                       |
| Total mass of particles   | 13         | 45  | 8.1  | 13          | 45  | 15.5 | 0.988                       |
| Beta-glucan mass          | 13         | 139 | 9.6  | 13          | 25  | 36.1 | 0.184                       |
| Endotoxin mass            | 13         | 116 | 16.6 | 13          | 113 | 18.4 | 0.973                       |
| Total bacteria number     | 13         | 7   | 3.9  | 13          | 11  | 2.9  | 0.329                       |
| Fungal spores number      | 13         | 20  | 8.7  | 13          | 25  | 9.4  | 0.756                       |
| ANOVA                     | p=0.015    |     |      | p=0.174     |     |      |                             |

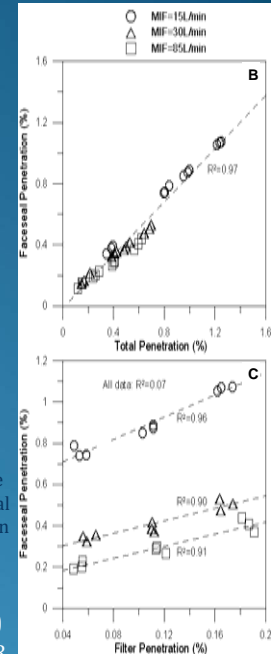
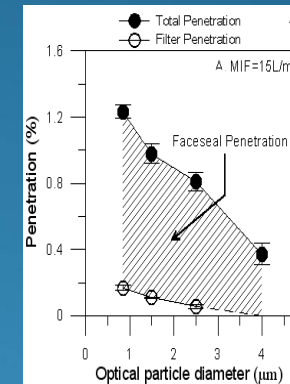


Figure 3. Penetrations at different particle size (A) and correlations between face seal and total (B) and between face seal and filter penetration (C).

- WPFs for ER were statistically different between different particle types (Table 1)
- No difference in WPF between ER vs. FFR
- Faceseal penetration >> filter penetration (Fig 3A)
- Both filter and faceseal penetration decreased with increase in particle size (Fig 3A)
- Faceseal penetration correlated with total penetration independent of MIF (Fig 3B). Faceseal penetration correlated with filter penetration only when analyzed separately for each MIF (Fig 3C)

## Conclusions

- Field study showed that differences in WPFs may be larger between different types of contaminants than between two respirator types
- Realistic faceseal leakage for manikin experiments was established based on WPF results from field study
- Manikin-based set-up will be used for investigating faceseal leakage of biological particles



# Innovations in Respirator Design and Fit Testing

Lisa M Brosseau

University of Minnesota, School of Public Health, Division of Environmental Health Sciences



## Introduction

### Research Goals

What is the current state of technology and what are the future research needs and challenges for developing and certifying air purifying respirators with improved fitting characteristics?

### Research Tasks

1. Explore innovations in respirator design and fit test methods to better understand the incentives and barriers for improvements.

2. Develop and present a one-day workshop focused on exploring current respirator design issues, new ideas and areas where research could lead to better fitting half-facepiece respirators.

### Timeline

- Contract awarded March 2008
- Workshop held November 2009
- Presentations posted on internet January 2009
- Final Report expected June 2009 (will be available on the University of Minnesota website)

### Research Questions

1. What are the most important innovations in respirators in the recent past – and what contributed most to their development and success?
2. Are there inventions that have not proved to be commercial successes?
3. Has the pace of innovation in respiratory protection slowed in recent years, and if so, why?
4. Do current regulatory, economic or political conditions prevent new innovations in respiratory protection?
5. Are there research directions or regulatory approaches that could encourage further innovation?
6. What combination of regulation, research and manufacturer innovation might lead to more “user-friendly” respirators?
7. Do respirator manufacturers understand the needs of current and future users?
8. Are there barriers that prevent manufacturers from responding quickly to users’ needs?
9. Have manufacturers failed to apply or recognize technological improvements from other fields?
10. Are users looking for improvements for which technology does not yet exist?

## Methods

### Selecting Innovations

#### • Advisory Board

#### • Survey of health and safety professionals

Innovations in the past 40 years that did and didn’t lead to significant improvements in respirator fit.

#### Successful Innovations (n=16)

|                                                                                                |  |
|------------------------------------------------------------------------------------------------|--|
| <b>Facepiece Materials</b>                                                                     |  |
| Silicone and other similar flexible polymer facepiece materials (9)                            |  |
| <b>Elastomeric Respirator Facepiece Designs</b>                                                |  |
| Head harness or cradle for straps (6)                                                          |  |
| Double or triple flanges or flaps for sealing peripheries (2)                                  |  |
| Ratchets for harness assemblies (2)                                                            |  |
| Foam materials in facial sealing area (1)                                                      |  |
| Using “yoke” to attach headband to facepiece (1)                                               |  |
| Improvements in attachment of cartridges to facepiece (1)                                      |  |
| Using center section of hard plastic to reduce weight and cost and make connections easier (1) |  |
| Rhombus-shaped cartridges offset out of field of view (1)                                      |  |
| Easy and quick bayonet mounts for cartridges (1)                                               |  |
| Single strap design across cross-section of facepiece (1)                                      |  |
| Adjustable straps with numbers at adjustment points (1)                                        |  |
| Latch on half mask respirator (1)                                                              |  |
| Drop down feature (respirator hangs around neck when not in use) (1)                           |  |
| Ergonomic design of face seal (1)                                                              |  |
| <b>• Cartridge Designs</b>                                                                     |  |
| Increase in cartridges for specific gases (1)                                                  |  |
| Multi-contaminant cartridges (1)                                                               |  |
| <b>Other Respirator Design Aspects</b>                                                         |  |
| Better speech transmission (3)                                                                 |  |
| Multiple size facepieces (2)                                                                   |  |
| Self-monitoring devices (1)                                                                    |  |
| Fit check button on valve or filter (1)                                                        |  |
| Use of anthropometric data to design facepieces (1)                                            |  |
| Increase in respirator makes and models (1)                                                    |  |
| Elimination of quarter mask (1)                                                                |  |
| <b>Filter Design</b>                                                                           |  |
| Electrostatic filter media, decreased pressure drop (7)                                        |  |
| <b>Filtering Facepiece Design</b>                                                              |  |
| Flat fold filtering facepiece respirators (2)                                                  |  |
| Filtering facepiece respirators (3)                                                            |  |
| Molded “around the nose” area instead of metal strip (2)                                       |  |
| Supporting filter media to prevent collapse during moisture buildup (1)                        |  |
| Exhalation valves for filtering facepiece respirators (1)                                      |  |
| Closed-cell foam on nose area (1)                                                              |  |
| <b>Fit Testing</b>                                                                             |  |
| Quantitative fit testing (3)                                                                   |  |
| Portacount (4)                                                                                 |  |
| Reliable qualitative fit tests for particulate filters (4)                                     |  |
| LANL panels (1)                                                                                |  |
| Quantitative fit test adapters (1)                                                             |  |
| Negative pressure fit test method (1)                                                          |  |
| <b>Other</b>                                                                                   |  |
| Centralized respirator medical evaluation, training, fit testing for unions (1)                |  |
| <b>Regulatory Changes</b>                                                                      |  |
| NIOSH seal on cartridges (2)                                                                   |  |
| End of service life programs (1)                                                               |  |
| Modification of the NIOSH face dimensions panel (1)                                            |  |
| OSHA revised standard (1)                                                                      |  |

#### Less Successful Innovations (n = 16)

|                                                 |                                                                |
|-------------------------------------------------|----------------------------------------------------------------|
| <b>Elastomeric Respirator Facepiece Designs</b> | <b>Other Respirator Design Aspects</b>                         |
| Adjustable pneumatic sealing periphery (3)      | Scanning faces to design respirators (2)                       |
| Replaceable face seals (2)                      | Measuring devices with each box of masks (1)                   |
| Adhesive on sealing surface (1)                 | One size fits all (1)                                          |
| Breath responsive respirators (1)               |                                                                |
| Personal face-forming face seal (1)             |                                                                |
| Ultra-soft face seal or gel seal (1)            | <b>Cartridge Designs</b>                                       |
| Multiple head harness adjustment points (1)     | End of service life indicator for organic vapor cartridges (1) |
| Face seal inserts (1)                           | End of service life indicators (1)                             |

### Advisory Board

Nicole Vars McCullough, PhD, CIH, 3M Occupational Health and Environmental Safety Division, St Paul, MN

Alan Hack, MA, CIH, CSP, Los Alamos, NM (retired)

Jeff Weed, Weed Respiratory Protection Solutions, LLC, White Bear Lake, MN

Peter Nelson, Silent Power, Inc. and Breathe Safely, Baxter MN

Janice Bradley, International Safety Equipment Association, Arlington VA

Howard Cohen, PhD, CIH, University of New Haven, New Haven, CT

Jeff Birkner, PhD, CIH, Moldex Metric Inc., Culver City, CA  
Bill Borwegen, Occupational Health and Safety Director, Service Employees International Union, Washington DC

Curt Hering, Equipment Services, Toronto EMS

Mark Catlin, Service Employees International Union, Washington DC

### Successful Innovations

- Ambient aerosol quantitative fit test method
- Strap cradle or head harness
- Double flanged facepiece
- Flat fold design for filtering facepiece respirators

### Less Successful Innovations

- Adhesive face seal
- User seal checks

### No Fit Test Respirator Workshop November 6, 2008 Pittsburgh PA

Presentations and Breakout Session summaries available at:

<http://cpheo.sph.umn.edu/cpheo/mcohs/courses/nofit/home.html>

## Results

### EXAMPLE

#### Ambient Aerosol Quantitative Fit Test Method

#### Incentives

- Automated, easy-to-use method
- Eliminate the need to generate a test aerosol
- Portability, accuracy, reliability
- Quantitative results – higher fit factors
- Method that could be used by field personnel

#### Costs of R&D and Commercialization

- Approximately \$1 million to develop and test the original prototypes
- Additional money was spent to commercialize
- Additional funds to develop final specifications prior to purchase of field instruments
- Costs of ongoing tests and design improvements

#### Effect on Respirator Use and Regulation

- Revolutionized quantitative fit testing, making it an acceptable and eventually expected aspect of many respirator programs.
- OSHA agreed that anyone using this method would receive a *de minimus* violation (no fine)
- Eventually, method was added to the 1998 OSHA respiratory regulation

#### Effect of Regulations on Innovation

- The OSHA asbestos standard required the use of quantitative fit testing for respirator use

#### Reasons for Success

- Cost effective (approximately \$6000)
- Simple to use
- Produced quick and accurate results
- Portable
- Used ambient aerosols

#### Effect on Better Fit

- More discrimination between different respirators (models and sizes)
- Can be used with broad range of respirator designs

This project was funded by NIOSH contract HHSD2542008M24720P. The findings and conclusions in this poster are those of the author and do not necessarily reflect the views of the National Institute for Occupational Safety and Health.

## Conclusions

What makes respirator innovations successful?

1. Technology push
  - a. New technologies
  - b. New materials
  - c. New approaches or methods
2. Market pull
  - a. Customer requests and needs
  - b. New markets and users
  - c. New uses and applications
3. Published research
4. Health and safety professionals
5. Regulatory agencies

• Innovation continues, but there are economic, regulatory, technologic and knowledge barriers.  
• There are still a number of areas where respirator design and fit testing could benefit from further research.

## Recommendations

### More research is needed on:

- Positive and negative pressure seal checks
- Filtering facepiece designs
- Facepiece seal technologies
- Relationship between facepiece fit and facial characteristics
- Designs that can be frequently donned and re-donned without losing good fitting properties
- Effectiveness of strap designs
- Trade-off between protection and comfort
- Continuous fit check methods
- Effects of aging
- Interactions of respirators with other types of personal protective equipment
- Materials and designs that work in a broad range of environmental conditions

### Also recommend these activities:

1. Advisory panel(s) representing key stakeholders
2. Formal collaborations with government agencies to combine resources
3. Formal assistance to inventors and small businesses
4. An advisory committee that performs regular review of certification regulations with respect to new technology or methods
5. More opportunities for interactions between internal NIOSH researchers and external investigators

# Bioaerosol Test Systems for Studying Respirator Decontamination

Edward Fisher<sup>2</sup>, Evanly Vo<sup>1</sup>, Samy Rengasamy<sup>1</sup>, and Ronald Shaffer<sup>1</sup>

<sup>1</sup>NIOSH/NPPTL, Pittsburgh, PA, <sup>2</sup>EG&G Technical Services, Pittsburgh, PA

## Introduction

The threat of an influenza pandemic requires the development of strategies to alleviate possible shortages of NIOSH approved N95 filtering facepiece respirators (FFRs) in the healthcare community. One possibility is to decontaminate and reuse disposable FFRs. However, test methods for the evaluation of decontamination procedures for air-permeable materials such as FFRs are lacking. In this study, test systems were developed to apply virus-containing particles to FFRs for the purpose of decontamination testing. The Bioaerosol Respirator Test System (BARTS) generates virus-containing droplet nuclei. The Droplet Particle Aerosol Respirator Test System (DPARTS) generates virus-containing droplets.

## Experimental Approach

### Virus (Coliphage MS2) Loading of FFR Samples

#### BARTS

- Droplet Nuclei-small desiccated particles (*Air-Circulating Virus*).
- Applies virus to 6 FFR coupons.
- Vacuum pulls particles into filter medium.

#### DPARTS

- Droplet- particles with increased size and water content (*Sneezing/Coughing*).
- Applies virus to full respirator sample.
- Particles sprayed directly on the surface. (No vacuum).

### Decon. Treatments of Varying Degrees of Severity

#### BARTS

- Bleach.
- Ultraviolet germicidal irradiation (UVGI).
- Integrated antimicrobial technology.

#### DPARTS

- Bleach.
- Ultraviolet germicidal irradiation (UVGI).
- Integrated antimicrobial technology (*future study*).

### Virus Enumeration and Efficacy Determination

- Plaque Assay.
- Log Reduction Determination.



### Evaluation

- Assess the ability to differentiate between the efficacy of decontamination treatments of varying degrees of severity for BARTS and DPARTS loaded FFR samples.
- Preliminary comparison of the efficacy of decontamination treatments for virus applied with BARTS and DPARTS.

Fig 1. Schematic of the experimental approach for the evaluation of BARTS and DPARTS

## Results

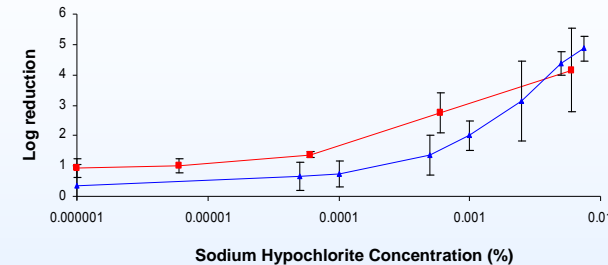


Fig 2. Efficacy of sodium hypochlorite (bleach) decontamination on FFR samples challenged with MS2 in the form of droplet nuclei (BARTS) (■) and droplets (DPARTS) (▲). The lines represent the average log reduction of MS2 on 3 samples excised from a single model for each concentration of bleach.

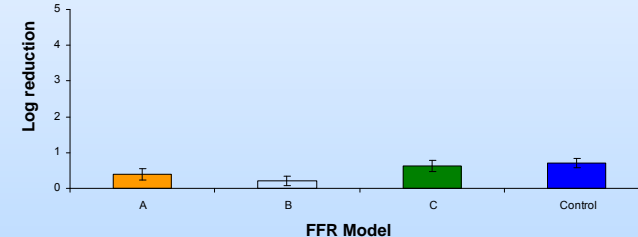


Fig 4. Efficacy of FFR models with integrated antimicrobial technology (A-C). Samples of FFR models containing unique antimicrobial technology and a control model were challenged with MS2 in the form of droplet nuclei (BARTS) and stored at 22°C and 30% RH. The bars represent the average log reduction of MS2 on six FFR samples after 20 hours. The six samples were excised from at least 3 FFRs for each model.

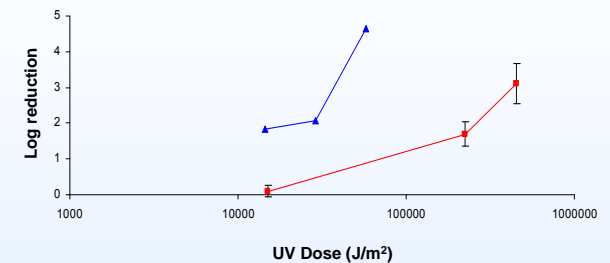


Fig 3. Efficacy of a UVGI decontamination on FFR samples challenged with MS2 in the form of droplet nuclei (BARTS) (■) and droplets (DPARTS) (▲). The lines represent the average log reduction of MS2 on 3 FFR samples excised from a single model for each dose of UVGI.

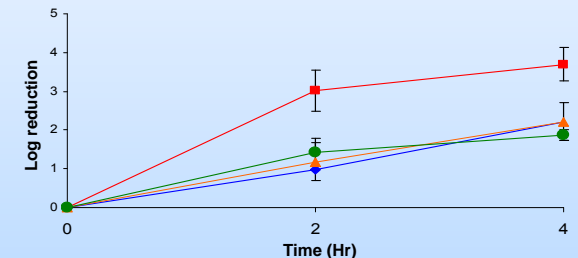


Fig 5. Efficacy of FFR models with integrated antimicrobial technology (A-C). FFR models A (▲), B (■), C (●) and a control (◆) were challenged with MS2 in the form of droplet nuclei (BARTS) and stored at 37°C and 80% RH. The lines represent the average log reduction of MS2 on 6 FFR samples for each time point. The six samples were excised from at least 3 FFRs for each model.

## Conclusions

- The method of virus application onto FFRs may affect the efficacy of decontamination procedures.
- Accurate evaluations of decontamination procedures for FFRs may require the use of both droplet and droplet nuclei systems.
- Antimicrobial technologies were ineffective against MS2-containing droplet nuclei under typical room temperature and room relative humidity conditions but may demonstrate increased efficacy under other environmental conditions.

## Future Direction

- Perform more experiments to better compare of the characteristics of BARTS and DPARTS
- Test FFRs containing antimicrobial technologies with enveloped viruses which may be more readily inactivated.
- Collaborate with the Air Force Research Laboratory to develop ASTM test methods for viral decontamination of air-permeable materials using a droplet method (work item# 19888) and a droplet nuclei method (work item# 19887).

Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.





# Factors Affecting Respirator Tolerance- (Respirator Research at UCLA)

P. Harber MD MPH, S. Bansal MD, S. Santiago MD, D. Liu BS, D. Yun BS, S. Wu BA BS, Y. Liu MD MS- University of California, Los Angeles. (pharber@ucla.edu)

Funding: NIOSH/ CDC R01 OH8119

**WILL RESPIRATORS BE EFFECTIVE?**  
DEVICE MUST EFFECTIVELY SUPPLY CLEAN ENOUGH AIR  
DEVICE MUST BE USED WHEN AND WHERE NEEDED

- QUESTIONS:**  
CAN WORK CONTINUE IF WIDESPREAD USE IS NEEDED?  
CAN PERSONS WITH MILD RESPIRATORY DISEASES USE THEM?  
HOW DO 2 COMMON TYPES COMPARE?  
WHAT IS BEST MEASURE OF "PUBLIC HEALTH EFFICACY?"

**TWO APPROACHES:**  
**DECISION ANALYSIS:** DEVELOP A QUANTITATIVE DECISION MODEL FOR EXPRESSING "TRADE-OFFS" IN PROGRAM DESIGN  
**EXPERIMENTAL:** EXPERIMENTS TO EMPIRICALLY ANSWER SPECIFIC QUESTIONS

**EXPERIMENTAL APPROACH**  
**COMPARE 2 RESPIRATOR TYPES** AND LABORATORY SURROGATES  
► N95 ► DUAL CARTRIDGE HALF MASK (HF) ► INDIVIDUAL LOADS (INSPIRATORY RESISTANCE, EXPIRATORY RESISTANCE, DEAD SPACE)

**IN 4 USER GROUPS:** NO RMAI; COPD; RHJ; NITIS; ASTHMA.

**UNDER 3 CONDITIONS:**  
MODERATE EXERTION SIMULATED WORK; LOW EXERTION SIMULATED WORK; PULMONARY EXERCISE LABORATORY

**MULTIPLE OUTCOME MEASURES:**  
PHYSIOLOGIC RESPONSE: VENTILATION, TIDAL VOLUME, ETC.  
PHYSIOLOGIC ADAPTATION: ADAPTATION OF RESPIRATORY PATTERN  
WORK PRODUCTIVITY  
MASK POSITION MOVEMENT  
SUBJECTIVE RESPONSES

## METHODS: DETAILS

**PROTOCOL**  
EACH SUBJECT PARTICIPATED FOR 3 DAYS: ► WORK SIMULATION-N95 ► WORK SIMULATION HF ► EXERCISE LABORATORY-SURROGATES LOADS

**ANALYSIS METHOD:** MIXED MODEL REGRESSION FOR EFFECTS OF  
► RESPIRATOR TYPE ► DISEASE TYPE ► DISEASE\*RESPIRATOR INTERACTION ► PERSONAL CHARACTERISTICS (AGE, GENDER, FEV1, ANXIETY)

**MEASUREMENT TECHNIQUES**  
RIP: RESPIRATORY INDUCTIVE PLETHYMOGRAPH (MEASURES BREATHING WITHOUT CONNECTION TO MASK)

**SUBJECTIVE RESPONSES:** 12 SEPARATE ITEMS  
**PRODUCTIVITY DURING 8 SIMULATED TASKS:** SPEED & ACCURACY

**VIDEO RECORDING:** MASK REPOSITIONING ETC.

**SUBJECTIVE SCALES** (Borg 6-20)  
(eg BREATHING, HEAVY, HOT...)



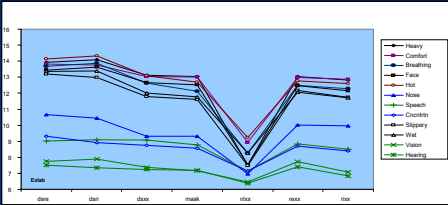
## WORK TASKS

| Task        | Code  | Site's action                                                                    | End site      | Respirator use            | Control action |
|-------------|-------|----------------------------------------------------------------------------------|---------------|---------------------------|----------------|
| Low n       | Low   | Familiarize sub oc with res procedure                                            | Low Mode a n  | Sitting/ Walking          | Mode a n       |
| Bolt        | Bolt  | So bolt in a bin                                                                 | Sedentary     | Sitting                   | Low            |
| Ca          | Ca    | Pick up and deliver bucket of rice                                               | Mode a n      | Bending/ Walking          | Low            |
| Cow         | Cow   | With oc on, cows, obtain paper and place in a paper bin                          | Low           | Upright/ Bending          | Mode a n       |
| Drive       | Drive | Simulate driving                                                                 | Sedentary     | Sitting                   | High           |
| Legs        | Legs  | Produce towel with plastic blocks following gross hand action                    | Sedentary     | Sitting                   | Mode a n       |
| Magne Stand | Magne | Place magnet on boards at proper coordinate line and on an action                | Low           | Above head level          | High           |
| Magne Walk  | Magne | Walk to bins to magnet then place on box at proper coordinate based on an action | Low/ Mode a n | Walking/ Above head level | High           |
| Sho         | Sho   | Shoek into a shoe with correct brace and in a jug (no video walking)             | Mode a n      | Walking/ Above head level | Mode a n       |

## MAJOR FINDINGS

**HOW SHOULD SUBJECTIVE RESPONSE BE MEASURED?**

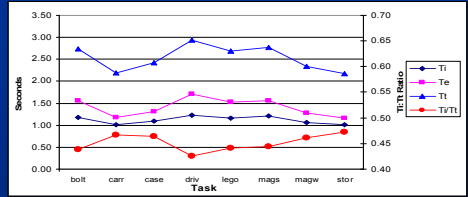
ONE QUESTION IS NOT ENOUGH:  
MULTIPLE SUBJECTIVE RESPONSES MUST BE MEASURED  
3 DISTINCT GROUPINGS OF RESPONSES:  
► "PHYSIOLOGIC IMPACT",  
► "FUNCTIONAL IMPACT",  
► "MINIMAL AFFECTED"



THE FIGURE SHOWS RESPONSES TO 12 SUBJECTIVE DOMAINS (EXERCISE LAB). THE VARIABLES NATURALLY CLUSTER IN 3 GROUPS.

**HOW SHOULD PHYSIOLOGIC RESPONSE BE MEASURED?**

ADAPTATION OF RESPIRATORY PATTERN IS THE MOST CONSISTENT EFFECT



| Variable | Respirator | End site | HF    | N95   | bol   | driv  | lego  | maga  | magne | case  | carr   | sto    | Resp | p Value | Task | In c n |
|----------|------------|----------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|------|---------|------|--------|
| Vt       | 0.92       | 0.91     | 0.77  | 0.72  | 0.80  | 0.76  | 0.91  | 1.21  | 1.02  | 1.12  | 1.02   | 1.12   | na   | <.0001  | na   |        |
| Ve       | 23.39      | 23.35    | 18.18 | 15.76 | 19.08 | 17.51 | 25.22 | 30.32 | 29.22 | 31.08 | na     | <.0001 | na   |         |      |        |
| Ri       | 24         | 24       | 24    | 24    | 24    | 25    | 21    | 31    | 33    | 33    | na     | <.0001 | na   |         |      |        |
| HR       | 86         | 86       | 80    | 80    | 80    | 82    | 88    | 88    | 94    | 96    | na     | <.0001 | na   |         |      |        |
| Ti       | 1.14       | 1.10     | 1.17  | 1.22  | 1.17  | 1.21  | 1.08  | 1.10  | 1.01  | 1.02  | <.0001 | <.0001 | na   |         |      |        |
| Te       | 1.39       | 1.44     | 1.57  | 1.71  | 1.63  | 1.58  | 1.38  | 1.31  | 1.18  | 1.18  | 0.0018 | <.0001 | na   |         |      |        |
| Tt       | 2.03       | 2.04     | 2.74  | 2.83  | 2.69  | 2.78  | 2.34  | 2.42  | 2.19  | 2.18  | na     | <.0001 | na   |         |      |        |
| TIT      | 0.46       | 0.45     | 0.44  | 0.43  | 0.44  | 0.44  | 0.46  | 0.46  | 0.47  | 0.47  | <.0001 | <.0001 | na   |         |      |        |
| Vt/T     | 0.85       | 0.88     | 0.69  | 0.61  | 0.72  | 0.66  | 0.91  | 1.12  | 1.08  | 1.14  | na     | <.0001 | na   |         |      |        |
| PRVt     | 1.90       | 1.93     | 1.19  | 1.00  | 1.20  | 1.15  | 1.58  | 2.08  | 1.83  | 1.99  | na     | <.0001 | na   |         |      |        |
| PRVt     | 1.39       | 1.35     | 1.05  | 0.83  | 1.12  | 1.03  | 1.44  | 1.90  | 1.69  | 1.88  | na     | <.0001 | na   |         |      |        |
| PRVt     | 50.26      | 50.46    | 51.13 | 49.03 | 50.83 | 50.76 | 50.26 | 50.77 | 50.17 | 50.11 | na     | <.0001 | na   |         |      |        |
| PRVt     | 48.71      | 48.32    | 45.44 | 43.10 | 46.93 | 45.21 | 47.66 | 47.20 | 48.52 | 48.47 | na     | <.0001 | na   |         |      |        |

THE TABLE SUMMARIZES RESULTS OF MIXED REGRESSION ANALYSES

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Harber P, Bansal S, Santiago S, Liu D, Yun D, Ng D, Liu Y, Wu S, Mai, domain Sub oc ve Response o Resp ator Use During Simu a ed Work. J Occup Env on Med 2009; 51:38-45  
Harber P, Ma Z, Ch K. Decision model o op ng resp a o p o oc on J Occup Env on Med 1999; 41:358-365  
Harber P, Liu D, S os M, Bloomer C, Santiago S, Resp a o f o oc During Simu a ed Res-Li e Ac y y Me thology. Am J Resp Ch Care Med 2007; 175 (supp 4 Pt1): 171

## SUMMARY

**HOW DO THE 2 RESPIRATOR TYPES COMPARE?**

- HF) PRODUCED MORE ADVERSE SUBJECTIVE RESPONSE ON MULTIPLE SCALES
- HF) PRODUCED GREATER PHYSIOLOGIC ADAPTATION IMPACT (ALBEIT LIMITED IN MAGNITUDE)

**IMPLICATIONS:**

BOTH THE DECISION ANALYSIS AND EXPERIMENTAL APPROACHES SUGGEST:

► THERE IS A "TRADE OFF" BETWEEN RESPIRATOR PROTECTION FACTOR AND PROTECTION OF WORKERS! I.E., HIGHLY PROTECTIVE RESPIRATORS THAT ARE NOT USED MAY ACTUALLY BE LESS PROTECTIVE TO PUBLIC HEALTH THAN LESS EFFECTIVE DEVICES THAT FAR BETTER TOLERATED & MORE WIDELY AVAILABLE

► SINCE WE DO NOT (YET) KNOW WHICH OUTCOMES ARE MOST IMPORTANT, RESPIRATOR DESIGN & EVALUATION SHOULD CONSIDER MULTIPLE DOMAINS: ► (PHYSIOLOGIC IMPACT, ► RESPIRATORY ADAPTATION, ► MULTIPLE SUBJECTIVE COMPONENTS, ► WORK PRODUCTIVITY, & ► ACTUAL UTILIZATION)

**DOES MILD DISEASE SEPRE CLUDE USE? (PARTIAL ANSWER)**

- NO, PERSONS WITH THE 3 MILD DISORDERS COULD EFFECTIVELY USE THE RESPIRATORS
- RESPIRATORY HEALTH STATUS DOES, HOWEVER, CHANGE THE EFFECT OF THE RESPIRATORS (IN THE REGRESSION MODELS, THERE WERE SIGNIFICANT INTERACTION TERMS BETWEEN RESPIRATOR TYPE AND DISEASE CATEGORY)

## DECISION ANALYSIS MODEL

**METHOD:**

DEFINE KEY FACTORS & TYPICAL VALUES

ESTIMATE # OF PERSONS OVEREXPOSED

DETERMINE IMPACT OF INCREMENTAL IMPROVEMENT OF 1 FACTOR ON # OVEREXPOSED

### FACTORS

#### RESPIRATOR

PF

WPF

#### SITES

NUMBER OF SITES

WORKERS/SITE

SITES IDENTIFIED

SITE HAS A PROGRAM

#### PROGRAM

PROPER SELECTION

RESPIRATOR AVAILABLE

#### PERSON

EVER USES

PROPORTION OF TIMES USED

#### EXPOSURE

EXPOSURE LEVEL

TYPICAL HAZARD LEVEL

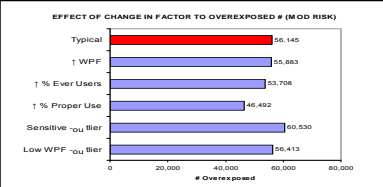
#### VARIABLE TY

% OUTLIERS

#### RESULTS

NO. ABOVE HAZARD LEVEL

DIFFERENCE



THE FIGURE SHOWS THE BENEFIT OF IMPROVING EACH FACTOR

**CONCLUSION:**

FOR MODERATE RISK SITUATIONS, THE BENEFIT OF IMPROVING PROPER UTILIZATION IS > BENEFIT OF IMPROVING PROTECTION FACTOR

# Respirator and Surgical Mask Protection from Cough Aerosols

W. P. King, W. G. Lindsley, C. S. Miller, J. D. Palcic, J. V. Szalajda, R. J. Vojtko, G. Walbert NIOSH

## Abstract

There is a need to know how well surgical masks and disposable filtering facepiece respirators (FFR) protect wearers from cough generated aerosols as those seen in periods of respiratory infection activity. Few studies have been done to quantify the effect of their use on viral transmission. Controlled studies are needed to assess the efficacy of surgical masks and FFRs in preventing virus transmission. The project goal is to measure how well masks and FFRs protect healthcare workers from aerosols produced by cough simulator.

Surgical masks and FFRs corresponding to those in the Strategic National Stockpile will be used in the study and have been characterized. The breathing head form and sampling system has been constructed and verified. The cough aerosol exposure simulation includes a simulator that produces a simulated aerosol-laden cough through a coughing head form. A second breathing head form is connected to a breathing machine to simulate respiration of a healthcare worker and can be outfitted with PPE. Both head forms are located in an examination room exposure simulation which will simulate the cough of a patient and the respiration of a healthcare worker, and measure the amount of cough aerosol inhaled by the breathing head form with and without a surgical mask or FFR.

- Characterize penetration of surgical masks and N95 respirators used in study
- Develop methodology to simulate exposure of a health care worker to cough generated aerosols.
- Quantify the cough generated exposure environment.
- Measure the amount of aerosol potentially inhaled by a simulated worker with and without respiratory protection and the evaluate the effect of pertinent parameters

## Characterization of surgical masks and FFRs

### Outputs:

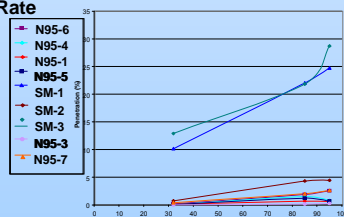
- Penetration (Ci/Co) and resistance for surgical masks and N95 respirators used in simulation

### Outcomes:

- The dependence of filter penetration on type (surgical mask or N95 respirator) and individual samples (make and model)
- Characterization of the effect of flow rate on filter penetration
- Estimation of the degree of variability in filter penetration within type and sample

## Aerosol Penetration versus Flow Rate

Samples of each surgical mask and FFR were checked for instantaneous penetration by NaCl aerosol and air flow resistance at three flow rates: 32, 85, and 95 Lpm. All NIOSH approved N95s met the approval criteria (penetration not to exceed 5% at 85 Lpm). Surgical mask samples had a significantly greater penetration.



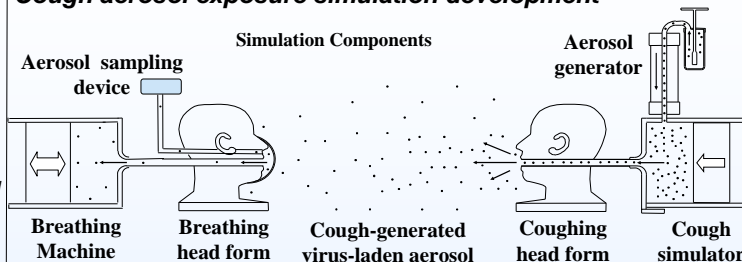
## C<sub>i</sub>/C<sub>o</sub> for masks and FFR sealed to breathing head forms

Samples of each mask were also sealed to test head forms and the ratio of outside aerosol concentration, C<sub>o</sub>, to inside aerosol concentration, C<sub>i</sub>, were determined using a TSI Portacount. The overall average was 82 for N95 respirators and 10 for surgical masks.

These values will serve as benchmarks for the sealing of surgical mask and FFR samples in the simulation studies.

| Mask/FFR | Average | std. dev. |
|----------|---------|-----------|
| N95-1    | 136     | 8.31      |
| N95-2    | 66      | 43.25     |
| N95-3    | 107     | 0.53      |
| N95-4    | 91      | 1.41      |
| N95-5    | 101     | 12.08     |
| N95-6    | 49      | 20.41     |
| N95-7    | 24      | 10.84     |
| SM-1     | 6       | 0.58      |
| SM-2     | 17      | 4.95      |
| SM-3     | 7       | 0.71      |

## Cough aerosol exposure simulation development



## Breathing head form and sampling system

### Interim outputs and milestones:

To reduce backside leakage into the breathing machine an elastomeric seal was developed and fitted into the original piston.

Breathing waveforms (see below) for the simulation experiments were developed and verified.

Head forms were modified to accommodate aerosol sampling devices.

A method for sealing surgical masks and FFR to head forms was selected.

Operating procedures for the breathing head form have been compiled.



Computer-controlled linear motor drive of breathing machine can produce various waveforms for breathing head form

Aerosol samples are collected from the head form breathing zone

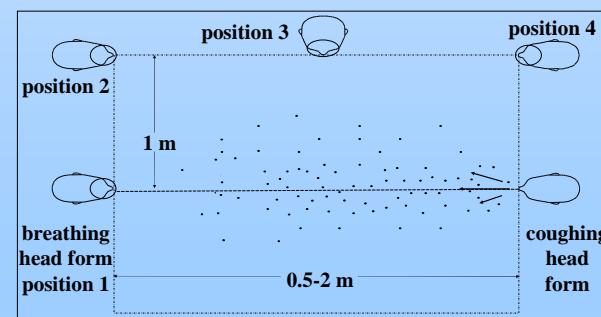
### Simulation breathing waveforms

| minute volume        | rate               | tidal volume |
|----------------------|--------------------|--------------|
| L·min. <sup>-1</sup> | Min. <sup>-1</sup> | mL.          |
| 32                   | 21.5               | 1500         |
| 85                   | 29.8               | 2857         |
| 100                  | 35                 | 2857         |

Both the breathing head form and sampling system and coughing head form and cough aerosol generation system are currently being installed in the examination room exposure simulation.

## Cough aerosol exposure simulation

### Examination room exposure simulation layout



## Cough aerosol exposure simulation parameters

| Parameter      | Levels | Description of levels                     |
|----------------|--------|-------------------------------------------|
| Mask/FFR type  | 10     | No mask, 3 surgical, 7 N95                |
| Location       | 6      | 6 locations as shown in figure above      |
| Coughing       | 2      | 1 cough/15 minutes, or 1 cough/30 minutes |
| Breathing rate | 3      | 3 breathing waveforms (see table)         |

### Outputs:

- Determination of the viral particle filtration performance of masks and respirators and significant differences among type (surgical mask or N95 respirator) and individual samples (make and model)

- Evidence of the degree of increased protection (reduction in viral particle penetration) that different masks and respirators provide as compared to wearing no mask or respirator

- The degree of correlation of filtration performance (from initial characterization) for each mask and respirator with the viral particle filtration performance

### Outcomes:

- Establish a greater understanding of the efficacy of surgical masks and FFR when exposed to aerosols generated by a cough simulator

- Enable NIOSH to provide research-based recommendations for effective respiratory protection strategies for surgical masks and FFR in healthcare settings

## Stakeholders

Occupational Safety and Health Administration, Environmental Protection Agency, Food and Drug Administration, World Health Organization, National Institute for Occupational Safety and Health and other Center for Disease Control groups

## Disclaimer

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

# Simulated cough-generated aerosol particle penetration through masks and respirators

William G. Lindsley, Robert E. Thewlis, Jeffrey S. Reynolds and Ernest S. Moyer  
National Institute for Occupational Safety and Health, Morgantown, West Virginia, USA [wlindsley@cdc.gov](mailto:wlindsley@cdc.gov)

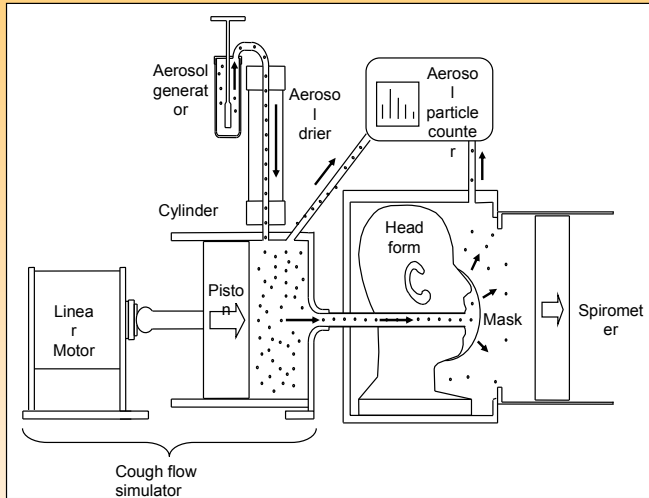
## Introduction

- Airborne disease transmission is of great concern because of the pandemic potential of avian influenza and SARS and the increasing prevalence of drug-resistant strains of tuberculosis.
- Many respiratory diseases can be spread by the infectious aerosols produced when sick individuals cough, sneeze, speak or breath [1,2].
- Cough-generated aerosols are especially important because coughing is a ubiquitous symptom of respiratory infections [3].
- Larger aerosol particles produced during a cough impact or settle quickly onto nearby surfaces where they can be transferred to people by touch. Small particles dry rapidly and tend to stay airborne for an extended time, allowing them to be inhaled by individuals who are many meters away [4].
- The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommend that patients with infectious respiratory illnesses wear surgical or procedure masks whenever they might infect others, such as during transport. CDC also recommends that, when respiratory infections are widespread in the community, patients who are coughing should be offered masks when they first arrive at a health-care facility [5-7].
- However, it is unclear how effective surgical and procedure masks are at reducing infectious aerosol release, particularly for smaller aerosol particles. This is especially true for cough-generated aerosols; many studies of masks have examined particles expelled while breathing and speaking, but very few studies have looked at the ability of masks to block cough-generated aerosols even though coughing produces much greater particle concentrations and higher air velocities than normal breathing or speaking [8-9].
- The purpose of this project is to study the ability of masks and respirators to block small cough-generated aerosol particles.

## Acknowledgements

- The authors would like to thank Dr. Ali Afshari, Dr. David G. Frazer and Dr. Brian T. Chen for ideas and discussions related to this project. We would also like to thank machinist David H. Edgell for his skillful production of many of the parts used in this system. The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

## Methods

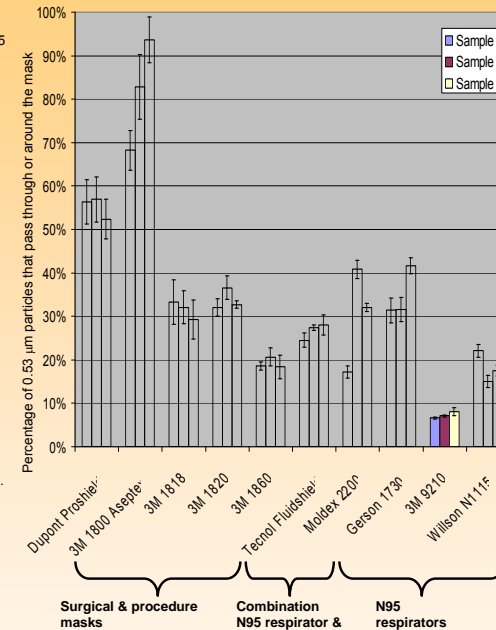


### Detailed Materials and Methods

- Masks and respirators:** Masks and respirators were selected to provide a variety of designs and manufacturers and were purchased commercially. All respirators and masks of a given type were from the same lot to eliminate lot-to-lot variability. The respirators and masks were tested as received from the manufacturer without humidity pretreatment. All tests were conducted at room temperature.
- Test aerosol:** Masks and respirators were tested using 0.53  $\mu$ m latex microspheres (Dow Diagnostics). Microspheres were received in a liquid suspension. In glove use, the microspheres were sonicated and diluted sufficiently with deionized water to ensure that  $\geq 98\%$  of the microspheres would be aerosolized as single particles. Aerosolization was performed with a Model 3000 Aerosolizer (TSI) at 150 kPa (20 bar) jet pressure. The aerosolized microspheres were then passed through a diffusion drier (Model 3002, TSI) and mixed with bipolarly ionized diluent air (Model 9910, TSI) electrostatically to neutralize any accumulated charge on the aerosol.
- Cough flow simulator:** The cough flow simulator consists of a piston and cylinder driven by a computer-controlled linear motor. The piston and cylinder have a 25 cm diameter with a maximum displacement of 19 liters. The linear motor (Model 4020, California Linear devices) is controlled by a computer motor control card (MMC-2 Delta Tau Data Systems) with a custom program written using PwWin32 (Version 3.2.3.0, Delta Tau Data Systems). The motor displacement was monitored by a linear encoder incorporated into the motor.
- Head form and spirometer:** A standard head form (Model 420, Sierra Engineering Company) was modified to include a 2.25 cm inner diameter copper tube running horizontally through the mouth from the front to the back of the face, after attaching the mask to be tested, the head form was placed in a sealed acrylic box which was fastened to a spirometer (Infodyne Systems).
- Aerosol particle counter:** The aerosol concentration in the cylinder of the cough flow simulator and in the spirometer were monitored using an optical particle counter (OPC, Model 1100, Grimm Technologies). The OPC reported the aerosol concentration in 15 size bins, which allowed monitoring of the microsphere concentration without interference from smaller particles created by surfactant in the particle suspension.
- Flow profile for simulated coughs:** Previously, Goldsmith et al. [10] collected data on the air flow and volume produced by adults during a cough. In their work, each subject was asked to exhale completely, inhale as much as possible, seal their lips around a disposable cardboard mouthpiece, and cough forcefully using as much of the air in their lungs as possible. Air flow was measured using a Fleisch pneumotachograph, collected and processed using a custom-written computer program. This procedure was repeated three times per subject. Based on average of 17 control coughs (10 male coughs, 7 female coughs) from subjects with no lung disease, one representative cough was used that was closest to the average volume and peak flow rate. This cough has a 2.1 liter volume with a peak flow of 8.45 liters/sec and a mean flow of 2.64 liters/sec.
- Test procedure:** The mask or respirator was mounted on the head form and the system was assembled and tested for leaks. The spirometer was then purged until the particle concentration was negligible. The path leading from the cylinder to the head form and spirometer was closed and the piston of the cough flow simulator was moved to its starting position. The path from the aerosol generator into the cylinder was then opened and the aerosol generator was activated so that the test aerosol flowed into the cylinder. The aerosol concentration in the cylinder was monitored using the OPC mask. The path from the aerosol generator was closed and the path to the head form, mask, and spirometer was opened. The cough flow simulator then generated four simulated coughs, sending the aerosol into the mask. The mask was then sealed to the spirometer and measured the aerosol concentration in the downstream region beyond the mask. After measurements were completed, the spirometer was again purged until the particle concentration was negligible, and the test was repeated. Each mask or respirator was tested six times, three samples of each mask and respirator were tested.
- Data analysis:** To account for the dead space in the spirometer region downstream from the mask, the cough aerosol test procedure was performed without a mask or respirator. The difference in particle counts between the cylinder and the spirometer was used to correct subsequent mask and respirator tests for the aerosol dilution due to the dead space and any other losses in the system. Thus, for each particle size, the aerosol particle penetration through a mask or respirator was computed as:  
$$\text{Penetration} = \frac{\text{Aerosol particle concentration downstream} - \text{Aerosol particle concentration upstream}}{\text{Aerosol particle concentration upstream}}$$

## Preliminary Results

- Surgical masks, procedure masks, N95 respirators and combination N95 respirator/surgical masks are being examined.
- For each test, the system measures the upstream particle counts, coughs 4 times and then measures the downstream particle counts.
- Each cough has a 2.1 liter volume with a peak flow of 8.45 liters/sec and a mean flow of 2.64 liters/sec.
- The data shown are for experiments using 0.53  $\mu$ m polystyrene latex microspheres.
- Three samples of each mask or respirator were tested. Each bar shows the mean result from six tests of one sample. Error bars show the standard deviation.



### Masks and respirators used in this study

| Manufacturer   | Model                | Description                                                   | Metal nose strip? | Foam strip to seal around nose? | Ties or Straps      |
|----------------|----------------------|---------------------------------------------------------------|-------------------|---------------------------------|---------------------|
| DuPont         | ProShield            | Pleated polypropylene surgical mask                           | Yes               | No                              | 2 ties              |
| 3M             | Aseprite 1800+       | Molded surgical mask                                          | Yes               | No                              | 1 rubber strap      |
| 3M             | 1818                 | Pleated surgical mask                                         | Yes               | No                              | 2 ties              |
| 3M             | 1820                 | Pleated procedure mask                                        | Yes               | No                              | 2 elastic ear loops |
| 3M             | 1860                 | Combination N95 respirator and surgical mask                  | Yes               | Yes                             | 2 elastic straps    |
| Kimberly-Clark | Tecno Fluidshield    | Combination N95 respirator and surgical mask; duck-bill style | Yes               | No                              | 2 elastic straps    |
| Moldex         | 2200 N95             | N95 Respirator                                                | No                | Yes                             | 2 elastic straps    |
| Gerson         | 1730                 | N95 Respirator                                                | Yes               | Yes                             | 2 elastic straps    |
| 3M             | 9210                 | Fold-up style N95 respirator                                  | Yes               | Yes                             | 2 elastic straps    |
| Willson        | N1115 Saf-T-Fit Plus | N95 Respirator                                                | Yes               | Yes                             | 2 elastic straps    |

## Discussion

- In this system, both masks and respirators reduced the release of simulated cough-generated aerosols.
- The reduction in cough-generated aerosol release varies considerably depending upon the mask or respirator.
- The preliminary results indicate that, during a cough, a substantial number of small particles can escape beyond surgical and procedure masks by passing through the mask and/or by passing around the mask through gaps between the mask and face.
- Respirators provide better filtration than do surgical masks. However, coughing appears to push respirators away from the face, breaking the face seal and allowing particles to escape around the respirator. This effect appears to be more pronounced with respirators than with masks, probably due to the higher resistance to air flow in respirators. Elastic straps may also contribute to this effect by allowing greater mask or respirator movement.
- Future experiments will look at different particle sizes and at masks and respirators sealed to flat plates. The latter experiments will help determine what fraction of the test aerosol is passing through the mask or respirator and what fraction is bypassing the mask or respirator via leaks around the edges.
- Further research will lead to a better understanding of the factors affecting the ability of masks and respirators to block the release of cough-generated aerosols and lead to improved designs of masks intended to be worn by patients with respiratory infections.

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# Thermal Imaging Analysis of Filtering Facepiece Respirators Surface Temperatures

William Monaghan, Marc Roberge, Manivel Rengasamy, and Raymond Roberge, NIOSH/NPPTL, Pittsburgh, PA

## Objectives

- To use infrared (IR) camera technology to measure maximum surface temperature of N95 filtering facepiece respirators (FFRs) with and without exhalation valves (EV).
- To compare temperature measurements during the end exhalation phase of respiration at sedentary breathing volumes associated with adult males.



Fig. 1. N95 filtering facepiece respirator with and without exhalation valve (EV).

## Background

- Comfort is a major determinant of compliance with filtering facepiece respirator (FFR) use and is determined by breathing rate, breathing resistance, CO<sub>2</sub> retention, O<sub>2</sub> decrements, communication ease, psychological issues, and thermal sensations.
- Increased facial warmth beneath a FFR is uncomfortable, significantly increases the subjective perception of breathing difficulty, and a common reason for non-compliance with use.
- FFR models are available with exhalation valves, which can reduce facial warmth by decreasing resistance to the egress of exhaled air and the related heat.
- Prior studies have relied upon temperature probes placed on facial skin beneath the FFRs.
- Thermal imaging with IR cameras allows qualitative and quantitative temperature determination over a wide surface area or small regions.

## Methods



Fig. 2. Infrared experimental test set-up.

- An IR camera was used to monitor and quantify the maximum surface temperature of N95 FFRs with and without exhalation valves.
- A headform was attached to an Automated Breathing and Metabolic Simulator (ABMS). The ABMS was programmed for a breathing volume of 10 L/min and 14 breaths/min.
- Statistical Analysis – A paired t-test was used for comparison of the mean surface temperatures for evaluated models of N95 FFR with exhalation valves and their counterpart N95 FFR without exhalation valves, as well as for comparisons between manufacturers.

## Conclusions

- N95 FFRs with exhalation valves offered no advantage over N95 FFRs without exhalation valves in reducing the build up of respirator surface heat as determined by IR camera measurements at breathing volumes for a sedentary adult male over a one hour period.
- At sedentary breathing volumes, exhalation valves may not be activated.
- Human studies will be needed to confirm study findings.
- IR technology offers potential utility in evaluating this issue and a number of other issues associated with respiratory protective equipment use (e.g., respirator leaks, correlations of respirator temperature with facial heat, etc.).

## Output

Monaghan W, Roberge M, Rengasamy M, Roberge R. (2009) Thermal imaging comparison of maximum surface temperature on N95 filtering facepiece respirators with and without exhalation valves at sedentary breathing volumes. Submitted to the Journal of the International Society for Respiratory Protection.

## Results

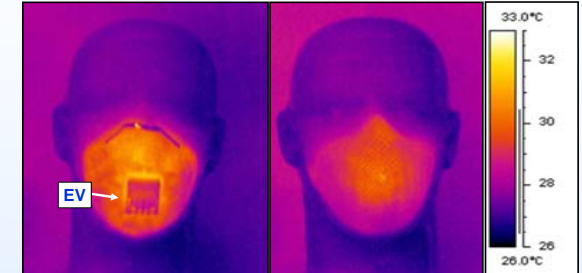


Fig. 3. Infrared images of N95 FFR/EV and N95 FFR

- The mean maximum surface temperature for all eight N95 FFRs with exhalation valves (30.44 °C) was higher than the mean for all eight N95 FFRs without exhalation valves (29.08 °C) [p=0.05].
- The mean maximum temperatures on the surface of the two models of N95 FFRs (29.69 °C, 28.47 °C) without exhalation valves and the two models of N95 FFRs with exhalation valves (30.61 °C, 30.26 °C) were not significantly different (p>0.05).
- No grossly visible movement of the exhalation valves was noted during the experiments.

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# N95 Filtering Facepiece Respirator Preparedness:

## Healthcare Field Study Findings

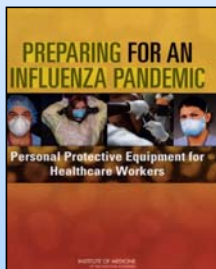
Debra A Novak, NIOSH/NPPTL, Pittsburgh, PA

### Introduction

- There is widespread consensus that an influenza pandemic is inevitable.
- Given the surge projections, medical goods will be necessary but scarce forcing hospitals to ration and reuse supplies.
- NIOSH certified N95 filtering facepiece respirators (FFRs) are considered to be an essential line of defense for healthcare workers (HCWs).
- Fragmented organizational planning efforts and poor FFR staff compliance signal the urgent need to better understand hospitals' capabilities for decontaminating respirators as well as ways to reinforce the proper use of FFRs for HCWs.
- NPPTL is investigating possible strategies for N95 filtering facepiece respirator reuse during a pandemic.
- This project presents information about pandemic preparedness initiatives and technologies to support filtering facepiece respirator decontamination.

### Project Goals

- To gain a clearer understanding of current pandemic preparedness efforts.
- To identify hospitals' viewpoints with regards to FFR decontamination.
- To determine hospitals' suggestions for the implementation of possible FFR decontamination and reuse procedures.
- To utilize project findings in the development and dissemination of technology transfer initiatives and to support future NIOSH research efforts.



### Methods

- Informal conversations with partners and stakeholders were undertaken to gain a general understanding of pandemic planning efforts.
- Based on conversations, specific eliciting questions were developed to gather information about hospitals' preferences for possible FFR decontamination and reuse.
- Snowball technique was used as a sampling method to gather informed views from healthcare organizations, distributors, manufacturers and oversight agencies.



### Preliminary Findings

- Hospitals' respiratory protection programs, FFR fit-testing and staff training procedures are **highly variable**.
- Qualitative** fit testing methods are reported to be more commonly used.
- Hospitals report a **wide range of pandemic preparedness efforts** that do not ensure universal HCW safety.
- Hospitals report plans that include "just in time" fit testing for thousands of employees and variable "on-hand" stockpiles of medical supplies.
- Non-governmental/private smaller and rural healthcare sectors** appear to be most vulnerable.
- Guidance documents are available in a variety of places yielding to **fragmented resources**.
- The healthcare workforce is an often **transient provider/worker group** who has been minimally involved in the pandemic preparedness initiative.
- Currently, there appears to be **limited adherence and intermittent use** by healthcare workers to recommended N95 FFR practices.
- HCWs **have not adopted** N95 respirator usage as a routine clinical practice.
- Hospitals' procedural preferences indicate that N95 decontamination should be a **low cost, quick and easy process that is completed by the worker**.
- Regulatory/accreditation enhancements supporting HCW respiratory protection are needed.

Therefore, the successful deployment of an N95 FFR decontamination and reuse procedure is dependent upon multifaceted approaches such as:

- enhancing hospital organizations' commitment to staff safety and training.
- raising staff awareness as to the importance of proper use.
- improving staff education to emphasize self assessment of proper fit.
- emphasizing HCWs' responsibility for personal safety.
- improving regulatory and accreditation oversight.

### Conceptual Model for Tech-Transfer



### Partners/Stakeholders

- Technical Support Working Group (TSWG)
- Healthcare Workers (HCWs)
- Healthcare Facilities
- Professional Organizations



### Future Work

- Develop a **concept of operations** for possible FFR decontamination and reuse
- Identify ways to **raise HCW awareness** of N95 FFR proper use
- Promote research aimed at understanding the effectiveness of **user seal checks** for N95 FFRs.
- Identify examples of **healthcare respiratory protection best practices**
- Organize a toolbox of **"proper use" guidelines and resources**

Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

# Demonstration and Sentinel Surveillance System for Ongoing and Continuous Monitoring of PPE Usage by Healthcare Workers (HCW) in the US.

Charles A. Oke, VMD, MPH, FACE

## Project Goals

- Determine the feasibility to identify, describe, develop, pilot, monitor and evaluate PPE surveillance systems used in a medical center setting.
- Track activities, resources and outcomes related to PPE and other infection control measures that would be used to control nosocomial transmissions of infectious diseases.
- Predict and track infectious disease outbreaks.
- Monitor indicators of PPT intervention strategies to record severity and duration of outbreaks.
- Assess the effect of enhancing timely PPE interventional response.

## Background

- The IOM Committee on PPE submitted in 2007 that during Pandemic Influenza HCWs will feel more secure only when PPE usage is as safe and effective as vaccines and medications.
- The value of monitoring and evaluating the activities and resources regarding PPE use among HCWs and safety prevention programs in major hospital systems has not been formally assessed.

## Stakeholders

- HCWs
- MANUFACTURERS
- AIHA
- HEALTHCARE FACILITIES
- OSHA
- ISEA
- ASTM

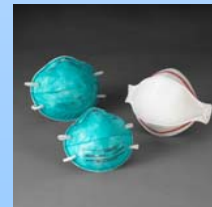


## Potential Partnerships

- VANDERBILT UNIVERSITY HOSPITAL SYSTEMS (VUHS)
- KESLEY-SEYBOLD HOSPITAL SYSTEMS
- DIVISION OF BIOTERRORISM PREPAREDNESS (CDC).

## Methods

- Establish an ongoing, continuous surveillance system in major hospital systems to function as a demonstration and sentinel system for PPE usage by HCW in the US.
- Provide full time infectious disease nurse/epidemiologist/program manager.
- Monitor the PPE (e.g. respirator) selection, use, fit, supplies, defects, audits, recalls and effectiveness in each of the selected facilities among healthcare workers; especially workers with direct patient care.
- Conduct a daily and ongoing active and passive surveillance using a standardized format and questionnaire.
- Data collected from self reports, audits, observational reports, compliance monitoring/evaluation, hazard prevention programs evaluation and disease transmission or non-transmission monitoring will be used for analysis and trending.
- The Early Aberration Reporting System (EARS) developed by CDC will be used to collect and analyze the data and monitor for trending and aberrant events.
- Data collected daily will be compiled on a weekly basis.
- When an event of interest occurs (e.g. lapses or disease transmission), investigation is initiated by the project officer.



## Next Steps

- Formalize Collaborations:
- Obtain Funding
- Enhance existing PPE inventory and use monitoring systems at partner facilities
- Roll the system out to 3 Large Hospital Systems in the Third year and beyond.

## Expected Outputs

- Describe/Document the evaluation and monitoring of PPE: selection, usage, non-usage, defects, fitting, periodicity and effectiveness of the respirators in the hospital environments.
- A functioning model that ensures hospitals are better prepared for Pandemic Influenza and other disasters (natural or man-made).
- Disseminate the findings in professional journals and present at appropriate conferences.

## Expected Outcomes

- Enhance timely interventional response during disasters such as Pandemic Influenza from hospital to hospital.
- PPE policies and standard operating procedures for first receivers (HCWs) and responders nationwide.

## Disclaimer

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# PHYSIOLOGICAL IMPACT OF THE USE OF N95 FILTERING FACEPIECE RESPIRATORS ON HEALTHCARE WORKERS

Raymond J. Roberge<sup>1</sup>, W. Jon Williams<sup>1</sup>, Aitor Coca<sup>1</sup>, Andrew Palmiero<sup>2</sup>, Jeffrey B. Powell<sup>2</sup>

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## Abstract

This study examined the physiological impact on healthcare workers of wearing N95 filtering facepiece respirators and N95 filtering facepiece respirators with exhalation valves for one hour at two work rates associated with the healthcare environment. The study also investigated associated changes in respirator microenvironment (dead space) mean oxygen and carbon dioxide levels. No significant differences were observed on measured physiological variables (heart rate, breathing rate, tidal volume, minute volume, oxygen saturation, transcutaneous carbon dioxide) between the two types of respirators at either work rate when compared to controls (healthcare workers not wearing a respirator). No significant differences were noted in respirator dead space mean oxygen and carbon dioxide levels for the different respirator models at either work rate. Modest increases in tidal volume and transcutaneous carbon dioxide levels were noted, but were not statistically significant. Wearing a N95 FFR or a N95 FFR/EV for one hour at work rates compatible with the healthcare environment imposes minimal physiological burden on healthy healthcare workers. Further studies are warranted to evaluate physiological effects on healthcare workers when filtering facepiece respirators are worn for more prolonged periods of time.

## Introduction

N95 filtering facepiece respirators (N95 FFR) are the most frequently recommended and used FFR in the healthcare setting. During the Severe Acute Respiratory Syndrome (SARS) outbreaks, healthcare workers frequently complained about symptoms associated with the use of FFR, including headaches, confusion, fatigue, and increased breathing rates that impacted performance and were suspected of being related to decreased oxygen ( $O_2$ ) and increased carbon dioxide ( $CO_2$ ) levels in the respirator dead space ( $V_{D, resp}$ ). Despite widespread use, there is little data on the physiological impact of N95 FFR on healthcare workers (HCWs). This study was undertaken to investigate the physiological burden of wearing N95 FFRs and N95 FFRs with an exhalation valve (N95 FFRs/EV) (from two manufacturers) on HCWs exercising at work rates consistent with those in the healthcare environment. The study also examined associated respirator microenvironment (e.g.,  $V_{D, resp}$ ) mean  $O_2$  and  $CO_2$  levels.

## Methods

- Ten healthy HCWs, experienced with FFR, were recruited and quantitatively fit tested for study N95 FFRs and N95 FFRs/EV.
- A LifeShirt® sensor vest was utilized for measuring heart rate (HR), respiratory rate ( $f_R$ ), tidal volume ( $V_T$ ) and minute volume ( $V_E$ )

## Methods (cont.)

- $V_{D, resp}$   $O_2$  and  $CO_2$  levels (mean of inhalation and exhalation) were monitored via a sampling port in the N95 FFRs at 18 samples/sec.
- Transcutaneous  $CO_2$  ( $tcPCO_2$ ) and oxygen saturation ( $SaO_2$ ) were monitored continuously by the Tosca 500 heated earlobe sensor.
- Subjects were treadmill-exercised without respirators (controls) for 15 minutes and with N95 FFRs and N95 FFRs/EV for one hour at rates identified as comparable to stationary work (1.7 mph) and nursing patient care duties (2.5 mph).
- Visual Analog Scales were used to measure comfort and exertion.
- At session end, subjects filled out questionnaires about issues subjectively associated with discomfort when wearing N95 FFRs.
- FFR were weighed before/after sessions for fluid buildup (water vapor, secretions).



Figure 1. LifeShirt® worn during treadmill exercising.



Figure 2. HCW wearing FFR during treadmill exercise.



Figure 3. Tosca transcutaneous  $CO_2$  sensor and pulse oximeter.

## Results

- There were no significant differences in HR,  $f_R$ ,  $V_T$ ,  $V_E$ ,  $SaO_2$ , and  $tcPCO_2$  for N95 FFRs and N95 FFRs/EV over one hour at either work rate when compared to controls.
- There were no significant differences for mean  $V_{D, resp}$   $CO_2$  and  $O_2$  values, respectively, at one hour for N95 FFRs (2.86%, 16.62%) and N95 FFRs/EV (2.92%, 16.68%).
- A modest (not statistically significant) increase in  $V_T$  (range, 42 mL – 167 mL) was noted with the use of N95 FFRs and N95 FFRs/EV at both work rates when compared to controls.
- Mean  $tcPCO_2$  levels increased with the use of N95 FFRs/EV at 1.7 mph (0.8 mm Hg) and at 2.5 mph for N95 FFRs (1.2 mm Hg) and N95 FFRs/EV (1.8 mm Hg); a decrease (1 mm Hg) was noted for N95 FFRs at 1.7 mph. Two subjects reached moderately elevated  $tcPCO_2$  levels (53 mm Hg, 57 mm Hg).

## Results (cont.)

- When compared to controls, there were no significant differences in comfort scores for N95 FFRs or N95 FFRs/EV at either work rate. When comparing FFR, N95 FFRs/EV were rated more comfortable than N95 FFRs at 2.5 mph ( $p=0.02$ ).
- No significant differences in exertion scores were reported between N95 FFRs and N95 FFRs/EV at either work rate. When comparing FFRs, significantly greater exertion was reported with N95 FFRs than N95 FFRs/EV at 2.5 mph ( $p=0.003$ ).
- Average weight gain for FFR per hour was 0.11 grams (no significant difference between respirator models).
- Reported FFR-associated phenomena included facial warmth, sweating, facial irritation, facial itching, pinching, difficulty breathing, dizziness, and lightheadedness.

Table 1. p-values for physiological variables comparing controls with wearing a filtering facepiece respirator (FFR), and comparing wearing filtering facepiece respirators (FFR) with wearing a filtering facepiece respirators with an exhalation valve (FFRs/EV).

| Condition        | Work rate | Respiratory rate | Heart rate | Tidal volume | Minute volume | SaO <sub>2</sub> | tcPCO <sub>2</sub> |
|------------------|-----------|------------------|------------|--------------|---------------|------------------|--------------------|
| Controls vs FFRs | 1.7mph    | 0.34             | 0.95       | 0.80         | 0.78          | 0.95             | 0.25               |
| Controls vs FFRs | 2.5mph    | 0.10             | 0.95       | 0.96         | 0.76          | 0.95             | 0.99               |
| FFRs vs FFRs/EV  | 1.7mph    | 0.83             | 0.06       | 0.27         | 0.23          | 0.54             | 0.76               |
| FFRs vs FFRs/EV  | 2.5mph    | 0.46             | 0.19       | 0.27         | 0.84          | 0.95             | 0.77               |

## Conclusions

- The use of N95 FFRs or N95FFRs/EV, for periods up to one hour at work rates common to the healthcare environment, results in only minor physiological impact on healthy HCWs.
- Mean  $V_{D, resp}$   $CO_2$  levels were higher and  $O_2$  levels lower than the OSHA standard for ambient atmospheres (i.e., 19.5%  $O_2$ , 0.5%  $CO_2$ ) [currently, OSHA ambient standard does not apply to respirator microenvironments].
- Minor (not statistically significant) increases in  $tcPCO_2$  and  $V_T$  can be expected with FFR use during the first hour at low work expenditures.
- Additional study will be required to investigate the physiological burden of FFR use on HCWs over more prolonged work periods (i.e., >1 hour).

## Disclaimer

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# Automated Breathing and Metabolic Simulator (ABMS) Evaluation of N95 Respirator Use with Surgical Masks

Edward J Sinkule, M.S., NIOSH/NPPTL, Pittsburgh, PA

## Project Goals

Use an ABMS-based test to evaluate the inhaled carbon dioxide (CO<sub>2</sub>) and oxygen (O<sub>2</sub>) concentrations and breathing resistance of NIOSH-approved N95 particulate filtering facepiece respirators (FFR) with and without a FDA-cleared surgical mask as a protective cover.

## Stakeholders

- Respirator manufacturers
- Health care workers
- FDA
- ISO
- Emergency responders
- CDC
- IOM

## Background

- In the United States, more than an estimated 90 million N95 FFR would be used by health care workers for each wave of an influenza pandemic.
- The increased reliance on N95 FFR would severely strain or exhaust respirator supplies.
- IOM recommendation: The useful life of N95 FFR could be extended by adding a surgical mask protective cover.
- Previous research has reported higher CO<sub>2</sub> and lower O<sub>2</sub> concentrations in N95 FFR alone (see references)\*.
- Currently, no NIOSH certification test is available to measure inhaled CO<sub>2</sub> and O<sub>2</sub> concentrations in non-CBRN air-purifying respirators.



## Methods

- At least four samples were tested on each of 31 NIOSH-approved N95 FFR models (includes those with and without exhalation valves). All tests were repeated with a FDA-cleared surgical mask protective cover for a total of 256 tests.

- Respirator models were selected from those used in the U.S. Strategic National Stockpile (SNS), and based upon market share. One surgical mask was selected from the SNS.
- All tests were conducted using the ABMS, which simulates human metabolism, minute ventilation, and breathing waveforms. The ABMS CO<sub>2</sub> protocol consists of the following levels of O<sub>2</sub> consumption, CO<sub>2</sub> production, and minute ventilation performed consecutively for a minimum of five minutes each: 0.5, 0.4, and 10 L/min STPD; 1.0, 0.8, and 25 L/min STPD; 1.5, 1.3, and 38 L/min STPD; 2.0, 1.9, and 62 L/min STPD; 2.5, 2.5, and 70 L/min STPD; and 3.0, 3.1, and 80 L/min STPD, respectively.

## Results

Table 1. Means of Respiratory Variables for 31 N95 FFR Models by Workload

| Oxygen Consumption (L/min) | Average Inhaled CO <sub>2</sub> (%) | Average Inhaled O <sub>2</sub> (%) | Peak Exhalation Pressure (mmH <sub>2</sub> O) | Peak Inhalation Pressure (mmH <sub>2</sub> O) |
|----------------------------|-------------------------------------|------------------------------------|-----------------------------------------------|-----------------------------------------------|
| 0.5                        | 2.8                                 | 17.0                               | 7                                             | -5                                            |
| 1.0                        | 2.0                                 | 18.4                               | 10                                            | -11                                           |
| 1.5                        | 2.4                                 | 18.1                               | 14                                            | -18                                           |
| 2.0                        | 1.6                                 | 19.2                               | 23                                            | -34                                           |
| 2.5                        | 1.4                                 | 19.4                               | 20                                            | -34                                           |
| 3.0                        | 1.7                                 | 19.1                               | 23                                            | -40                                           |

*Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.*

Table 2. Means of Respiratory Variables for 31 N95 FFR with Surgical Mask Cover by Workload

| Oxygen Consumption (L/min) | Average Inhaled CO <sub>2</sub> (%) | Average Inhaled O <sub>2</sub> (%) | Peak Exhalation Pressure (mmH <sub>2</sub> O) | Peak Inhalation Pressure (mmH <sub>2</sub> O) |
|----------------------------|-------------------------------------|------------------------------------|-----------------------------------------------|-----------------------------------------------|
| 0.5                        | 3.0                                 | 16.7                               | 8                                             | -7                                            |
| 1.0                        | 2.0                                 | 18.4                               | 11                                            | -14                                           |
| 1.5                        | 2.3                                 | 18.2                               | 17                                            | -23                                           |
| 2.0                        | 1.7                                 | 19.0                               | 29                                            | -42                                           |
| 2.5                        | 1.6                                 | 19.2                               | 25                                            | -42                                           |
| 3.0                        | 1.9                                 | 18.9                               | 30                                            | -51                                           |

## Conclusions

- Generally, average inhaled CO<sub>2</sub> decreased and average inhaled O<sub>2</sub> increased with increasing oxygen consumption in FFR and FFR with surgical mask cover.
- Peak exhalation pressure and peak inhalation pressure increased with increasing oxygen consumption, but more so in FFR with surgical mask covers.
- Compared to N95 FFR without surgical mask cover, higher average inhaled CO<sub>2</sub> were observed in 4 of 6 workloads among N95 FFR with surgical mask cover.
- Additional analysis is needed to investigate the effect(s) from respirator exhalation valves and among types of N95 FFR.

## References\*

- Turner, N., E. Sinkule, S. Hota (2003). Automated Breathing and Metabolic Simulator (ABMS) CO<sub>2</sub> Test for Powered and Non-Powered Air-Purifying Respirators, Airline Respirators and Gas Masks. National Occupational Research Agenda Symposium, Arlington, VA.
- Sinkule, E. and Turner, N. (2004). Inhaled Carbon Dioxide and Oxygen Concentrations in Three Escape Hood Respirators During Rest and Exercise. *Medicine & Science in Sports & Exercise* 36: S245.

# Evaluation of the Filtration Performance of 21 N95 Filtering Facepiece Respirators after Prolonged Storage

Dennis Viscusi,<sup>1</sup> Mike Bergman,<sup>2</sup> Edward Sinkule<sup>1</sup> and Ronald Shaffer<sup>1</sup>  
<sup>1</sup> NIOSH/NPPTL, Pittsburgh, PA, <sup>2</sup> EG&G Technical Services, Pittsburgh, PA

## Abstract

Organizations are stockpiling respirators to prepare for an influenza pandemic. To understand better the effects of prolonged storage, this investigation evaluated the filtration efficiency of 21 different models of National Institute for Occupational Safety and Health (NIOSH)-certified disposable N95 filtering facepiece respirators (FFRs). These respirators had been stored in their original packaging for a period of at least six years in research laboratories and warehouse facilities, ranging in temperature between 15 °C and 32 °C and relative humidity between 20 % and 80 %. Filter penetration was measured using an abbreviated version of the NIOSH respirator certification test. Of the 21 respirator models tested in this study, 19 models had both average initial and maximum penetration results of less than 5%. Mean initial penetration values ranged from 0.39% to 5.83%, whereas mean maximum penetration values ranged from 0.95% to 5.83%. There did not appear to be any correlation between the length of storage and failure to pass the filtration test. Results indicate that most N95 FFRs stored for up to ten years at warehouse conditions will likely have expected levels of filtration performance and that the degree of filtration efficiency degradation is likely model specific.

## Introduction

- Concerns exist over a possible pandemic-induced shortage of disposable N95 FFRs for infection control
- Organizations worldwide are stockpiling N95 FFRs
- Stockpiling FFRs is a relatively new phenomena
- Does prolonged storage adversely affect the filtration performance of N95 FFRs?



## Methods

- FFRs stored in their original packaging for at least 6 up to 10 years in research laboratories and warehouse facilities were evaluated for filtration performance
- Filtration performance (initial and maximum filter aerosol penetration and filter airflow resistance) were measured using an abbreviated version of the NIOSH respirator certification test
- A TSI Model 8130 Automated Filter Tester (AFT) (TSI Inc., St. Paul, MN) was used for all filtration performance data collection



TSI Model 8130 AFT

## Results

Table I. TSI 8130 AFT Means and standard deviations (SD) for filter airflow resistance at maximum penetration (mmH<sub>2</sub>O), % initial penetration (Init. Pen.) and % maximum penetration (Max. Pen.) for 21 N95 FFRs measured after prolonged storage.\* Note: **Bold values in red font** exceed the 5% NIOSH certification penetration criterion for N95 FFRs.

| Manufacturer | Model        | Resistance<br>(mm H <sub>2</sub> O) |      | Init. Pen. (%) |      | . Pen. (%)  |      |
|--------------|--------------|-------------------------------------|------|----------------|------|-------------|------|
|              |              | Mean                                | SD   | Mean           | SD   | MaxMean     | SD   |
| Tecnol       | PFR95-210    | 9.70                                | 1.25 | 0.94           | 0.14 | 1.05        | 0.17 |
| Gerson       | 2737         | 10.43                               | 0.64 | <b>5.83</b>    | 1.05 | <b>5.83</b> | 1.05 |
| Willson      | 1410N95      | 30.07                               | 3.76 | 2.91           | 0.72 | 2.94        | 0.75 |
| Willson      | N9501M       | 11.17                               | 0.38 | 1.53           | 0.39 | 1.56        | 0.41 |
| Willson      | N9510M       | 11.20                               | 1.28 | 0.95           | 0.27 | 0.95        | 0.27 |
| AOSafety     | 50257        | 12.37                               | 0.80 | 1.24           | 0.19 | 1.25        | 0.19 |
| 3M           | 8210         | 12.23                               | 0.06 | 0.65           | 0.05 | 2.15        | 0.19 |
| Moldex       | 2207N95      | 8.67                                | 0.15 | 3.85           | 0.72 | 3.88        | 0.72 |
| 3M           | 8212         | 17.13                               | 2.31 | 1.19           | 0.98 | 2.39        | 1.46 |
| Moldex       | 2300N95      | 11.43                               | 1.29 | 4.00           | 0.37 | 4.00        | 0.37 |
| 3M           | 8512         | 22.03                               | 2.83 | 0.39           | 0.11 | 0.98        | 0.46 |
| San Huei     | SH3810       | 16.90                               | 1.11 | 1.82           | 0.39 | 2.36        | 0.47 |
| Willson      | N9520FS      | 16.30                               | 0.46 | 0.77           | 0.40 | 1.01        | 0.26 |
| North        | 7175N95      | 12.63                               | 0.15 | 3.94           | 0.09 | 3.94        | 0.09 |
| US Safety    | ADN95        | 20.80                               | 0.52 | 2.12           | 1.10 | 2.24        | 1.32 |
| Survivair    | 1930         | 7.40                                | 0.10 | 1.41           | 0.13 | 1.41        | 0.13 |
| Moldex       | 2700N95      | 14.03                               | 0.49 | 1.84           | 0.02 | 1.84        | 0.02 |
| Magid        | KR795        | 12.13                               | 0.23 | <b>5.44</b>    | 1.95 | <b>5.59</b> | 1.97 |
| MSA          | Affinity Pro | 11.10                               | 0.53 | 1.26           | 0.30 | 1.26        | 0.30 |
| Sellstrom    | Econ-Air-NC  | 11.07                               | 0.38 | 2.81           | 0.49 | 2.84        | 0.49 |
| Draeger      | Piccola      | 10.50                               | 0.79 | 3.28           | 0.51 | 3.28        | 0.51 |

\* N95 respirators were loaded with NaCl aerosol until their maximum penetration was observed.

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## Study Limitations

- Study was not designed to be a typical aging experiment
  - True “before-and-after” comparisons were not possible
  - Assumed that products had < 5% filter penetration when purchased
- “Sample of convenience”
  - Only 21 of the 300+ commercially available FFRs were studied
  - Storage length varied from 6 to 10 years; not all FFRs were exposed to identical environment conditions for the same periods of time
  - FFRs available today may perform better or worse than the models included in the study

- Study only examined filtration performance

## Conclusions

- 19 / 21 (90.5%) of the N95 FFR models tested had average initial and maximum filter aerosol penetration levels < 5%
- Considering that all respirators were stored in their original packaging and experienced similar storage conditions, observations of filter aerosol penetration values > 5% were likely model specific
- Most N95 FFRs stored for up to 10 years in warehouse and laboratory conditions, similar to those of this study, will likely maintain their filtration performance following storage
- A formal aging investigation using carefully controlled conditions should be completed

## Recommendations

- Respirator stockpile administrators should consider contacting respirator manufacturers to determine if products in their stockpile have any specific storage requirements or shelf-life limitations
- In the absence of manufacturer guidance, administrators should consider periodic (perhaps annual) evaluation of a representative sample of products from their stockpile
- Where possible, incorporate product rotation (e.g., consume the oldest supplies first)

## Output

Viscusi DJ, M Bergman, E Sinkule, and R Shaffer, Evaluation of the Filtration Performance of 21 N95 Filtering Facepiece Respirators after Prolonged Storage. *American Journal of Infection Control*, In Press, Available online 1 February 2009



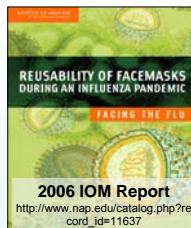
# Reusability of Filtering Facepiece Respirators

Ronald Shaffer<sup>1</sup>, Mike Bergman<sup>2</sup>, Edward Fisher<sup>2</sup>, Debra Novak<sup>1</sup>, Samy Rengasamy<sup>1</sup>, Dennis Viscusi<sup>1</sup>, and Evanly Vo<sup>1</sup>

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## Background

- During a pandemic, there will be an increased reliance on disposable N95 filtering facepiece respirators (FFRs) for infection control.
- >90 million N95 FFRs will be needed to protect workers in the healthcare sector during a 42-day outbreak. A respirator shortage is possible.
- The use of biological decontamination methods to render trapped infectious material inactive and allow respirator reuse has been suggested as a possible strategy to overcome a respirator shortage.
- IOM recommended studies on the effect of simple decontamination methods on respirator performance. NPPTL initiated research in 2006 to address IOM recommendations.



## NPPTL Research Project

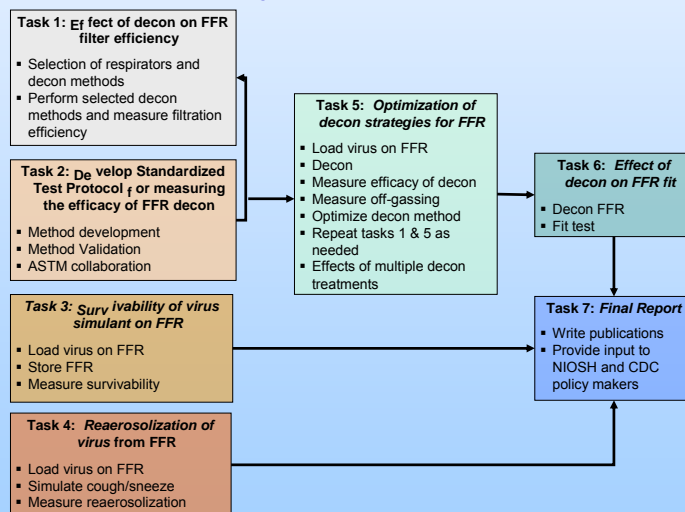


Figure 1. Overview of NPPTL Reusability of FFR Research Project

## Stakeholders

- Healthcare Workers & Administrators
- Pandemic/Infection Control Policy Makers
- Respirator Manufacturers

## Project Status and Preliminary Findings

### Task 1: Effect of decontamination on FFR filter efficiency

- Autoclave, 160°C dry heat, 70% isopropyl alcohol, and soap & water caused significant filter and/or physical degradation, while the effects of most other decontamination methods were found to be model specific.
- Although bleach and dry microwave treated FFRs exhibited expected levels of filtration performance, other effects such as odor (bleach) and melting (microwave) were problematic.
- UV, microwave generated steam, and moist heat (60°C, 80% RH, 4 hours) are considered to be the most promising methods for possible FFR decontamination and will be used for future studies.

### Task 2: Develop standard test protocols for measuring the efficacy of FFR decontamination

- Developed methods to apply virus (Coliphage MS2) to FFR samples as wet particles (droplets) and dry particles (droplet nuclei).
- Characterized the devices and validated decontamination efficacy using chemical (bleach) and physical (steam, UV) methods.

### Task 3: Survivability of virus simulant on FFR

- Initial tests conducted at 22°C and 30% RH demonstrate a 2.3 log(10) reduction in viable MS2 with 10 days of storage.
- More testing will be performed to include longer storage times and variable temperature and humidity conditions.
- FFR with integrated antimicrobial technology demonstrated no antiviral effect stored for 20 hrs. under typical hospital room temperature and room relative humidity (22°C and 30% RH).

### Task 4: Reaerosolization of virus from FFR

- Less than 1% of viable virus loaded onto the respirator were reaerosolized by the simulated cough.
- Fine aerosols of MS2 loaded onto the FFR were much more susceptible to reaerosolization than viruses loaded as relatively large droplets (>10 µm).
- Particles were reaerosolized following the first cough. Samples collected following the second or third coughs resulted in non-detections.



### Task 5: Optimization of decontamination strategies for FFR

- Currently evaluating decontamination methods in an effort to optimize treatment conditions.
- The aim is to find the least aggressive set of conditions that effectively inactivate the virus for promising decontamination methods from task 1.

### Task 6: Effect of decontamination on FFR fit

- Finalizing Human Subject Review Board protocol and training staff for fit test data collection.
- Performing resilience testing (e.g., tensile strength and elasticity) of FFR head straps following decontamination.

### Task 7: Final Report

#### Journal Publications (To Date)

- Task 1: Viscusi DJ, King WP, Shaffer RE. **Effect of Decontamination on the Filtration Efficiency of Two Filtering Facepiece Respirator Models.** *Journal of the International Society for Respiratory Protection*, (2007) 24: 93-107.
- Task 2: Fisher E, Rengasamy S, Viscusi D, Vo E, and Shaffer RE. **Development of a Test System to Apply Virus Containing Particles to Filtering Facepiece Respirators for the Evaluation of Decontamination Procedures.** *Journal of Applied and Environmental Microbiology*, (2009) E-Published ahead of print.

## Collaborations/Future Work

- NIOSH is participating in a Technical Support Working Group (TSWG) funded collaboration with the Air Force Research Laboratory (AFRL), Food and Drug Administration (FDA), University of Florida, and University of Nebraska Medical Center (UNMC). Key tasks include:

– AFRL will further evaluate the decontamination protocols using H1N1, a Biosafety Level 2 influenza. UNMC will perform evaluations with a low pathogenic strain of H5N1 influenza.

– ASTM test methods are being developed for viral decontamination of air-permeable materials (e.g., FFRs) using a droplet method (work item# 19888) and a droplet nuclei method (work item# 19887).

– A framework to transition the lab-based protocols from this project will be developed into workable solutions for hospitals, first responders, the Department of Defense, and possibly by private citizens for home use.

**Disclaimer:** The findings and conclusions of this poster have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

# ***Using OSHA Inspection Data for Surveillance of Problems with Respiratory Protection and Hearing Conservation Programs***

**Prepared by the RAND Corporation Center for Health and Safety in the Workplace (John Mendeloff, Elizabeth Steiner, Jessica Kopsic, Rachel Burns)**

**Under contract with the NIOSH National Personal Protective Technology Laboratory (NPPTL)**

# Dockable-Hybrid SCSR

## Bob Stein

### Background

Mine fires or explosions can have immediate and devastating lethal effects on those working nearby, but quite often other workers can find themselves having to travel through the devastated area in order to escape. In addition to low visibility and the possibility of facing a hazardous debris field, they will almost certainly face an atmosphere made un-breathable by combustion products, mainly carbon monoxide and oxygen concentrations insufficient to support life.

Lessons learned from the multiple mine disasters of 2006 underscored a long-standing desire to achieve breathing apparatus designs capable of providing a greater duration of respiratory protection to miners escaping from fires or explosions. Congress enacted new laws to help further assure that miners will be protected from the aftermath of fires or explosions, **the MINER Act of 2006**.

In a series of jointly sponsored technology exploration meetings which started in 2005, NIOSH NPPTL and the National Technology Transfer Center at Wheeling Jesuit University identified two promising concepts precisely for this purpose. One concept was for a hybrid SCSR, the other for a dockable SCSR.

### The Miner's Dilemma

A fire or explosion has occurred and I must escape. Do I need to don my breathing apparatus right now? I would rather save it until I know it is absolutely necessary to use it. If I put it on too soon, it may run out just when I need it most.



Miners "escape" in an experimental drill.



Mine explosion forces disrupt ventilation and create potential obstacles to escape progress. Post-explosion remains of a mine overcast litter an intersection.



Smoke billows from the portal of a mine that is on fire.

### Prior to the MINER Act

In fulfillment of the requirements at Title 30 Code of Federal Regulations, Part 75, it was required by MSHA that each coal miner was supplied with one Self-Contained, Self-Rescuer (SCSR), approved as a one-hour escape breathing device. In some locations with very long escape distances, more than one apparatus is provided with the additional SCSRs placed in storage locations along the intended path of escape.

### Post MINER Act

Since 2006 mine operators have been required by MSHA to provide each miner with two, one-hour escape, SCSRs, and it is uniformly required that additional one-hour escape devices be placed along the escape route at 30-minute travel intervals. This provides miners with far greater assurance that their emergency respiratory protection will last over the duration of the escape, but having multiple respirators requires changeover from one breathing device to the next in what might be an un-breathable atmosphere.

### Project Goal

Provide miners with an escape breathing device that will readily sustain them over the entire duration of an escape to the outside, or a place of relative safety regardless of travel distance within the mine.

### A New Approach



...yields seamless protection that can be tailored to the circumstances at hand to provide the necessary protection for the longest time period possible.



Docking valve, shown directly under mouthbit, with quarter-turn valve on front.

Switching from one type of protection to the other, or extending the duration by switching to a fresh component, can be accomplished without having to re-don the apparatus. Each component is fitted with a docking shoe that fits into the device docking port. The quarter-turn valve assures that the circuit is not open to ambient at any time, and that only one component at a time may be drawn upon. Once donned, the user's lungs remain protected from atmospheric contaminants according to the component type being used.

### Breathing Air Monitoring Capability

Integrated into a miner's cap lamp, the breathing air monitor (BAM) provides for continuous assessment of the ambient breathing environment. Designed to give visual warning for both elevated carbon monoxide, and insufficient oxygen, the BAM will allow miners a far greater level of certainty about when it is necessary to don respiratory protection. It will also indicate the level of protection needed should either of these common hazards develop along the escape route.



BAM using simple, "go/no-go" lights, will be incorporated directly into cap lamp.

### Expected Output

A dockable SCSR that will enable breathable-air options to a worn device without exposing the wearer to contaminated ambient atmosphere.

### Expected Outcome

The new SCSR will significantly improve the ability for miners to survive an underground mine fire or explosion. Today's SCSR's will provide only a finite amount of breathing air. New devices can provide a much longer supply limited only by the number of additional "add-on" supplies available.

### Technology Development Partners

Technical Products, Incorporated, Ayer, MA.  
TP Manufacturing, Incorporated, Ayer MA.  
3M Corporation, St. Paul, MN.  
NIOSH Mining Technology Office, Pittsburgh, PA

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# Advances in Chemical Sensing Allow Improvements in PPT

Debra J. Deininger, Synkera Technologies Inc.

Presented at NIOSH - NPPTL Pittsburgh PA, March 3, 2009

## Abstract

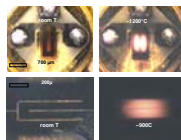
Synkera has developed a line of ultra-small and lightweight yet high performing chemical sensors. These sensors will allow advances in the functionality of PPT, leading to enhancements in worker health and safety.

One example of the implementation of Synkera sensors for improvements in PPT is active ESLI in respirators. A second example is the demonstration of single gas detection in a Smart Gas Card format. A third example is the improved reliability of detection through the use of multiple complementary sensor technologies.

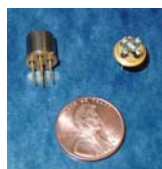
This poster describes the form and function of the Synkera sensors and offer examples of integration with PPT.

## Introduction

- A key limiting factor in the development of improved personal protective equipment are the limitations of conventional sensor technologies. Synkera addresses this need through development of advanced sensors based on complementary sensing approaches.
- Sensors are required that combine **high sensitivity and reliability**.
- Sensors must withstand challenging environmental conditions (e.g. temperature and humidity).
- Size and power consumption** is a critical challenge in the integration of sensor technologies with personal protective equipment.
- Communication of sensor response to wearer is important.
- Synkera has developed two new sensing platforms that can be used to make **improved measurements of hazardous gases**.



Microhotplates of two designs (400mW & 50mW @ 500°C)



Packaged microsensor

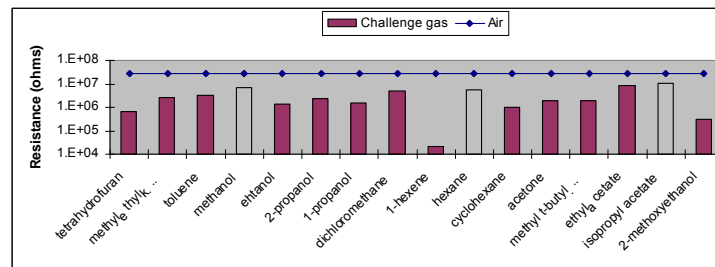


Electrochemical Sensors

## Method

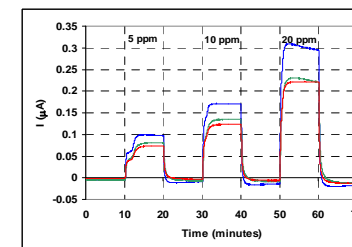
- Platform #1: Nanostructured micromachined ceramic substrate for chemiresistor and catalytic (pellistor) sensing.
  - Anodization of aluminum foils under precisely controlled conditions results in the formation of a nanostructured porous architecture (Fig.1 and Fig.2).
  - Pore diameters are controllable over the range of 5 to 300 nm.
  - Ceramic micromachining of the nanoporous substrate creates a ceramic microhotplate for use as a chemical sensing platform.
  - Application of sensing materials to the pores of the anodic alumina provides a high surface area host for sensor interactions with the environment.
- Platform #2: Solid state electrochemical sensors based on solid polymer electrolyte.
- Unique solid polymer electrolyte tolerates humidity extremes.
  - Small, low profile sensor design allows for integration of sensor into small spaces.
  - Sensor operates at room temperature for low power consumption.
- Chemiresistor sensors**
  - Utilize ceramic microhotplate.
  - Low power also enabled via advances in materials that allow reliable operation at lower temperatures than conventional semiconductor sensors.
    - Sensing based upon polymers and mixed metal oxides.
    - Material structure tailored at the nanoscale through *in situ* fabrication.
- Electrochemical sensors**
  - Sensors are based upon a unique solid polymer electrolyte, which allows reliable performance in a very small package.
- Catalytic combustible (Pellistor) gas sensors**
  - Feasibility demonstrated.
  - Low power enabled through the use of Synkera's ceramic microhotplate.
  - High surface area of nanoporous architecture will enable enhanced sensitivity and stability of sensing materials.

Non-Specific VOC sensor targeted at ESLI response to 100 ppm of organic compounds



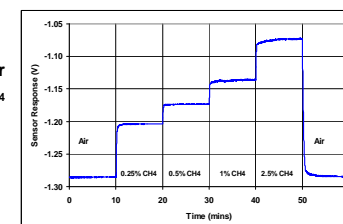
## Results

- Chemiresistive Detection**
  - VOC's
  - Flammable gases ( $H_2$ ,  $CH_4$ , etc.)
  - Toxic gases ( $H_2S$ ,  $NH_3$ ,  $Cl_2$ ,  $HCl$ , hydrides,  $NO_x$ , and many others)
  - Feasibility of ppb level detection demonstrated.
- Electrochemical Detection**
  - Carbon monoxide, hydrogen sulfide, selected VOC's
- Catalytic detection**
  - Methane and other flammable gases



Electrochemical sensor response to  $H_2S$

Pellistor sensor response to  $CH_4$



## Conclusions

- Ultra small, inexpensive broad band sensors could enable ESLI in respirators.
- Ultra small, inexpensive sensors enable advanced gas detectors in the form of Smart Gas Cards.
- Ultra small, inexpensive sensors enable multiple gas sensors applied to portable instruments to enhance reliability through redundant measurements.



# An Advanced Gas Sensor

John Kosek  
GINER, INC., Newton, MA

## Abstract

To measure the gaseous components of diesel exhaust underground, Giner, Inc. is developing a lightweight, compact low cost instrument that can simultaneously monitor CO, NO and NO<sub>2</sub>. In addition, since diesel engines require O<sub>2</sub> for the combustion process, the instrument will also monitor O<sub>2</sub> levels. Unlike other multi-gas sensors that require separate sensor cells for each gas, the novel feature of this instrument is the use of a single sensor cell to detect all 4 gases. This will result in a considerable cost savings, compared to commercially available instruments. The final instrument can either be a battery-powered, handheld, portable instrument, or can be designed to be mounted in a fixed location on a wall or suspended from the mine ceiling.

## Introduction

- The overall program objective is to fabricate a lightweight, low-cost multiple gas sensor to warn miners of the presence or absence of various underground gases. Gases to be monitored include CO, NO, NO<sub>2</sub> and O<sub>2</sub>.

- Specific program objectives include:

### Fabricate Advanced Sensor Cell Assemblies.

Novel thick-film sensors will be assembled that contain a unique membrane and a thick-film sensor chip with multiple electrodes to allow for multi-gas operation.

### Conduct Sensor Cell Testing

Identify basic operating parameters of the multi-gas sensor, including applied potential and sensing electrode catalyst. Determine linearity and the effect of humidity, temperature and interferences for each sensing electrode.

### Compare the Advanced Sensor Response to that of a Commercial Instrument

Compare the operating characteristics of the advanced sensor to that of a commercially-available MSHA-approved instrument.

### Conduct an Economic Analysis

Perform a preliminary economic analysis to predict the manufacturing cost of the multi-gas sensor.

## Methods

Fabricate advanced electrochemical sensors based on a thick film sensor chip in conjunction with a unique microporous membrane electrolyte. Through the use of screen printing and other deposition techniques, the composition of the sensing electrode catalyst can be changed to allow for the detection of four individual gases.

Selectivity to the various gases is obtained by the use of sensing electrode catalyst composition and sensing vs. reference electrode applied potential.

To increase thick-film sensor sensitivity, a membrane containing many laser-drilled holes is being utilized. This results in a 25-fold increase in triple point area while simultaneously decreasing the sensing electrode diameter by 90%. (The triple point is the gas-solid-liquid interface where the electrochemical reaction takes place.)

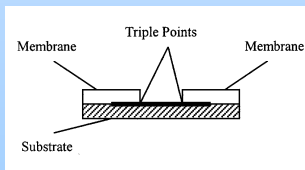
Thoroughly characterize the response to the individual gases with respect to:

- Linearity
- Effect of temperature
- Effect of humidity, and
- Effect of potential interferences.

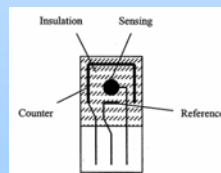
Compare the response of the advanced thin film electrochemical sensor chip to that of an MSHA approved instrument such as the MSA 5-Star Alarm (or equivalent). Parameters to be compared include those listed above.

Conduct an economic analysis to project the manufacturing cost of the advanced sensor cell. Parameters to be included are:

- Raw material cost,
- Membrane processing cost,
- Sensor fabrication cost,
- Circuit board manufacturing cost.

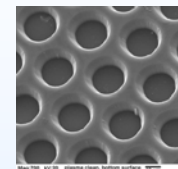


Baseline Thick- Film Sensor Chip  
(Side View)



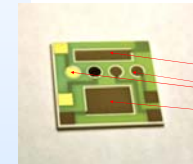
Baseline Thick- Film Sensor Chip  
(Top View)

## Results



Microporous Membrane Electrolyte

50% open  
20 micron holes



Advanced Thick Film Sensor Chip

One Reference Electrode  
Four Sensing Electrodes  
One Counter Electrode



Sensor Hardware

No moving parts – operates on diffusion  
Integral water reservoir (not seen)

## Disclaimer

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## Conclusions

- A microporous membrane electrolyte has been successfully prepared.
- Thick-film sensor chips have been fabricated.

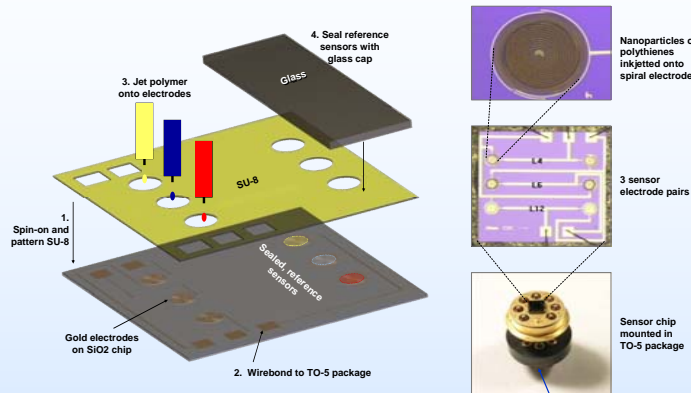
## Acknowledgement

This work is being supported by CDC/NIOSH Grant 1R43OH009016-01A2.

# Conductive Film-MEMS Chemical Sensors for Detecting Respirator Cartridge End-of-Service Life

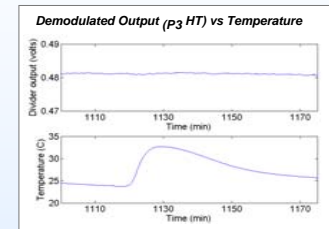
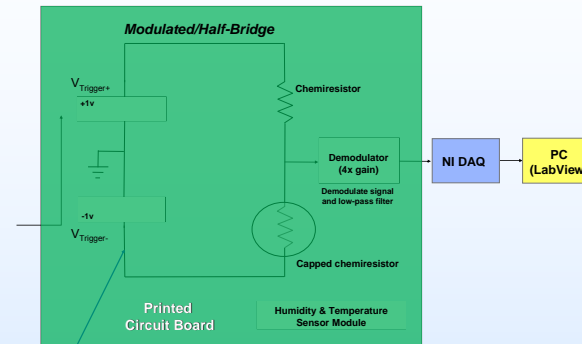
Jay Snyder, NIOSH/NPPTL, Pittsburgh, PA

## Sensor Chip



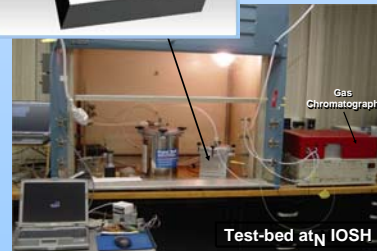
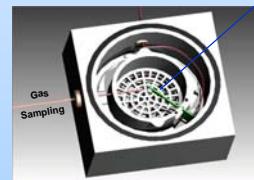
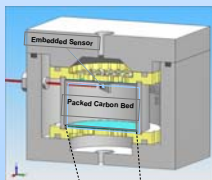
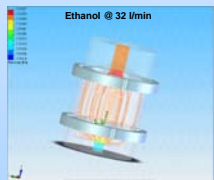
A sensor chip, packaged in a TO-5 housing, incorporates 3 matched sensor-pairs, each fabricated with a different polythiophene-based polymer or metal nanoparticle. Each sensor pair includes one device that is exposed to the analytes, and one capped device to act as a reference in a bridge circuit to minimize sensitivity to temperature variations. An SU-8 layer facilitates capping, and also seals exposed gold traces against humidity.

## Sensor Circuit



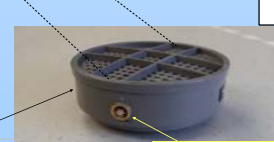
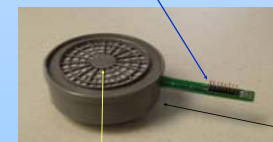
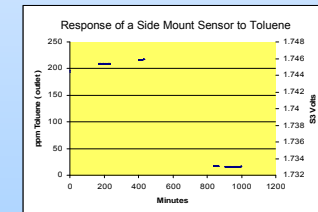
The TO-5 sensor package is mounted on a PCB containing sensor conditioning circuitry and a humidity & temperature sensor module. Matched sensor pairs are configured in a half-bridge to cancel common-mode temperature variations. The bridge is driven by a 1 Hz square wave, and the bridge output is demodulated to reject baseline sensor drifts (measured as 0.9%/day for P3HT divider). The output of the demodulator, which is amplified and filtered, and the outputs of the temperature/humidity sensors are interfaced to a PC through a National Instruments analog to digital card. The data is captured and further processed by LabView.

## Cartridge Simulator Test-Bed



A cartridge simulator test-bed has been developed to systematically evaluate sensors embedded within carbon filter beds. Gas analyte concentrations can be measured at specific locations in the beds using an adjustable gas chromatograph sampling tube. Computational fluid models can predict flow patterns to help predict expected distributions of analytes throughout the carbon bed.

## Preliminary Cartridge Testing



Sensors were provided to air purifying respirator cartridge manufacturers which were integrated into cartridges. The sensors utilized monolayer protected gold nanoparticles as the conductive layer. The cartridges were subjected to various conditions (toluene, trichloroethylene, enamel reducer, and relative humidities).

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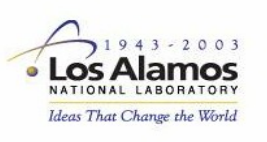
# Development of Predictive Models for Respirator Service Life

Jay Snyder, NIOSH/NPPTL, Pittsburgh, PA

## Project Goal

Develop mathematical models to predict respirator cartridge service lifetime

## Partnerships



## Background

- OSHA requires that service life determination for air-purifying cartridges be included as part of a respirator program.
  - OSHA Standard 1910.134(d)(3)(iii)(B)(2)
  - Employers are required to develop cartridge /canister change schedules
  - Use manufacturer recommendations
  - Mathematical models
  - Reliance on odor thresholds are not permitted as the primary basis for determining the service life
- Service life is affected by temperature, humidity, air flow through the filter, work rate, and presence of other chemicals.

## Method

Dubin-Radushkevich Equation

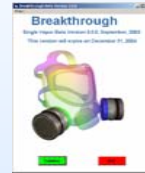
Equilibrium  $W_e$   
(g/g carbon)

$$W_e = W_o d_L \exp \left[ - \left( \frac{R T}{\beta E_o} \ln \frac{P}{P_{sat}} \right)^2 \right]$$

Reaction Kinetic  
form of the  
Wheeler-Jonas  
breakthrough time  
equation

$$t_b = \frac{W_e W}{Q C_o} - \frac{W_e \rho_B}{k_v C_o} \ln \left( \frac{C_o - C_b}{C_b} \right)$$

## Summary of Products



Website Web Page



CD Cover

Models Opening Pages

<http://www.cdc.gov/niosh/npptl/multivapor/multivapor.html>

## Outputs

- G. O. Wood, *Journal of Occupational and Environmental Hygiene* [2004]. "Estimating Service Lives of Organic Vapor Cartridges II: A Single Vapor at All Humidities", Volume 1(7), 472-492
- G. O. Wood, *Journal of Occupational and Environmental Hygiene* [2005]. "Estimating Service Lives of Air Purifying Respirator Cartridges for Reactive Gas Removal", Volume 2(8), 414-423
- G. O. Wood and J. L. Snyder [2007]. "Estimating Service Lives of Organic Vapor Cartridges III: Multiple Vapors at All Humidities," *Journal of Occupational and Environmental Hygiene* . Volume 4(6), 363-374.

## Outcomes

In the 48 months since the programs were made available in software form to be downloaded as a compliance assistance tool (along with a user-friendly video tutorial):

- It has been downloaded from the OSHA and NIOSH web pages more than 8,000 times
- There have been more than 38,000 visits to view the video or ask questions about the model
- 1000 CDs containing the model and the training video have been requested from NIOSH

## Future Work

- Work is currently underway to further develop Multivapor to be applicable to intermittent cartridge use.
- If funding permits, an investigation will be conducted to integrate Multivapor and GasRemove so that a model would calculate a service time for gases and vapors that are both chemisorbed and physically adsorbed.

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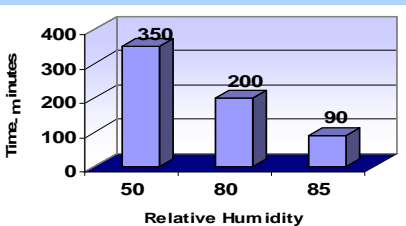


Figure 1. Effects of Relative Humidity on the estimated service time for 100 ppm Toluene

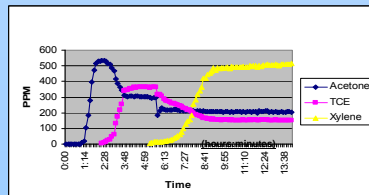


Figure 2. Breakthrough for Multiple Solvents

# Development and Integration of Sensor Technology for Determination of Respirator Service Life

Jay Snyder, NIOSH/NPPTL, Pittsburgh, PA

## Project Goal

Produce an intelligent respirator with end-of-service life indicator (ESLI) to determine when respirator performance will become affected due to contaminant breakthrough.

## Partnerships

- U.S. Air Force
- Carnegie Mellon U
- UC San Diego.

## Stakeholders

- Respirator manufacturers
- Emergency responders
- Industrial workers

## Background

- OSHA requires a change out schedule or ESLI for air-purifying respirator cartridges
- No ESLI available for organic vapors
- According to the 2001 NIOSH/BLS survey ~20% of establishments that use APRs allow their employees to determine respirator cartridge change out schedules

## Methods

- A two-phase approach has been taken involving collaborations with two universities: CMU and UCSD.
- Monolayer protected nanoparticle chemistry is being optimized. Photonic crystals are also being evaluated as an alternative approach

## Approach (Sensing Motifs)

### MicroElectroMechanical Systems (MEMS) - CMU

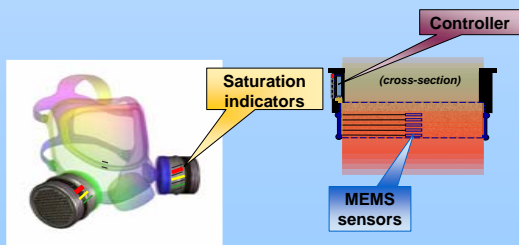


Figure 1. Concept depicting an air-purifying respirator with an integrated ESLI system

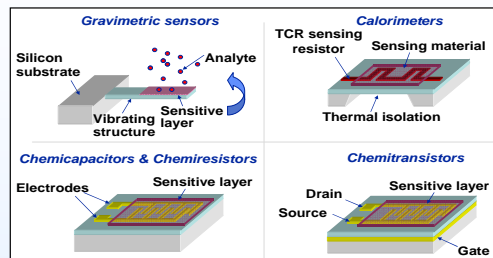


Figure 2. Multiple sensor types

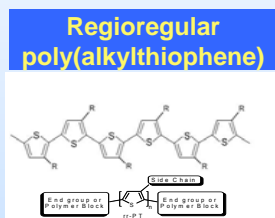


Figure 3. Family of conductive polymer compounds

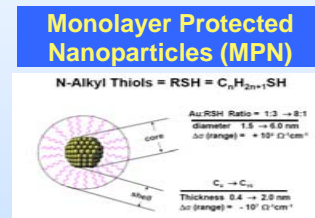


Figure 4. Basis for conductive Au nanoparticles

### Photonic Crystals – UCSD

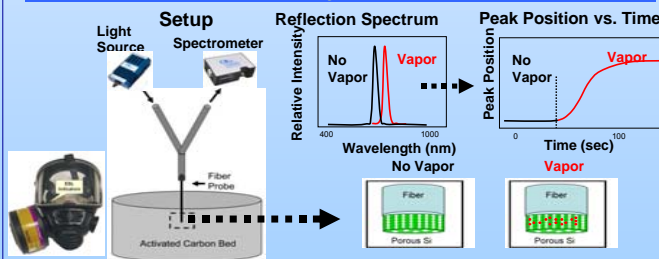


Figure 5. Lower left: Depiction of application as a gas mask end-of-service life sensor; Above/right: Experimental setup for in-situ monitoring of volatile organic compound (VOC) breakthrough in an activated charcoal filtration bed. Reflected light from an optical fiber-attached, embedded porous Si photonic crystal is monitored with a spectrometer

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## Preliminary Results (CMU)

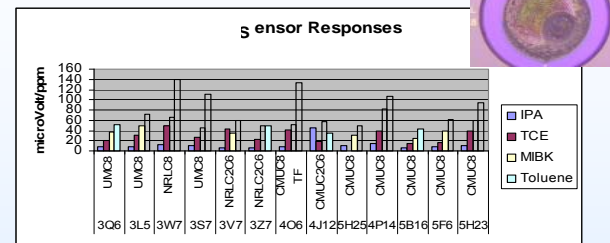


Figure 6. Sensitivity response of several monolayer protected gold nanoparticle films to solvents. A close-up view of the prototype ESLI chemiresistor sensor coated with nanoparticles is shown.

## Current Research

- ESLI sensor prototypes are being fabricated and tested against a suite of organic vapors and interferences (e.g., temperature, humidity).
- Partnerships with respirator manufacturers have been developed for the purpose of testing ESLI sensor prototypes integrated into cartridges. The first such testing has been completed.

## Outputs

Rose-Pehrsson et al [2005] Integration of Sensor Technologies into Respirator Vapor Cartridges as End of Service Life Indicators: Literature and Manufacturer's Review and Research Roadmap, NRL Report 6112-05-8875, May 6<sup>th</sup>, 2005.

McCullough et al [2005] Regioregular Polythiophene Nanowires and Sensors. *Proceedings of SPIE Vol. 5940*: 28-34.

Li et al [2006] Volatile Organic Compound Detection Using Nanostructured Copolymers. *Nano Letters* 6(8): 1598-1602

Li et al [2007] Inkjet printed chemical sensor array based on polythiophene conductive polymers. *Sensors and Actuators B* 123: 651-660.

King et al [2007] Optical fiber-mounted porous silicon photonic crystals for sensing organic vapor breakthrough in activated carbon. *Advanced Materials* 19: 4530-4534.